

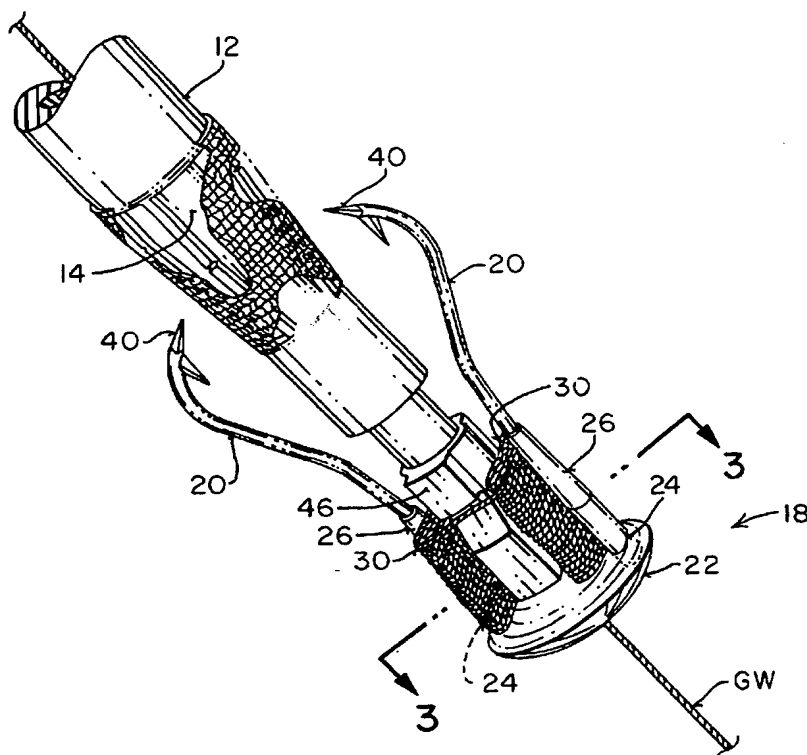
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(54) Title: VASCULAR PUNCTURE SITE SUTURING DEVICE AND METHOD

## (57) Abstract

A suture applying device (10) comprises a shaft (14) which carries a pair of needles (20) near its distal end. The needles (20) are joined by a length of suture (30), and the shaft (14) is used to both introduce the needles (20) into a lumen of a body structure and to push the needles back through tissue on either side of the puncture site. After the needles (20) have passed through the tissue, they are captured on the shaft (12) and drawn outward through the tract, leaving a loop of suture behind to close the puncture site near the body lumen. The suture (30) can then be tied and the knot pushed back through the tract to complete the closure. Alternatively, a locking fastener (100) formed of a resorbable material can be placed into the penetration over the sutures and the sutures tied over the fastener.



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## VASCULAR PUNCTURE SITE SUTURING DEVICE AND METHOD

BACKGROUND OF THE INVENTION5      1.      Field of the Invention

The present invention relates generally to devices and methods for the percutaneous closure of body lumens. More particularly, the present invention relates to devices and methods for the percutaneous closure of  
10      arterial and venous puncture sites, which are usually accessible only through a tissue tract.

A number of diagnostic and interventional vascular procedures are now performed transluminally, where a catheter is introduced to the vascular system at  
15      a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access which is usually established using the well known Seldinger technique, as described, for example, in  
20      William Grossman's "Cardiac Catheterization and Angiography," 3rd Ed., Lea and Febiger, Philadelphia, 1986, incorporated herein by reference.

When vascular access is no longer required, the introducer sheath must be removed and bleeding at the  
25      puncture site stopped. One common approach to attempt providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual or "digital" compression. This approach suffers from a number of disadvantages. It is  
30      time-consuming, frequently requiring one-half hour or more of compression before hemostasis is assured. This procedure is uncomfortable for the patient and frequently requires administering analgesics to be tolerable. Moreover, the application of excessive pressure can at  
35      times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression the patient is required to remain

recumbent for at least six and at times as long as  
eighteen hours under close observation to assure  
continued hemostasis. During this time renewed bleeding  
may occur resulting in bleeding through the tract,  
5 hematoma and/or pseudoaneurism formation as well as  
arteriovenous fistula formation. These complications may  
require blood transfusion and/or surgical intervention.  
The incidence of these complications increases when the  
sheath size is increased and when the patient is  
10 anticoagulated. It is clear that the standard technique  
for arterial closure can be risky, and is expensive and  
onerous to the patient. While the risk of such  
conditions can be reduced by using highly trained  
individuals, such use is both expensive and inefficient.

15 To overcome the problems associated with manual  
compression, the use of bioabsorbable fasteners to stop  
bleeding has been proposed by several groups. Generally,  
these approaches rely on the placement of a thrombogenic  
and bioabsorbable material, such as collagen, at the  
20 superficial arterial wall over the puncture site. While  
potentially effective, this approach suffers from a  
number of problems. It can be difficult to properly  
locate the interface of the overlying tissue and the  
adventitial surface of the blood vessel, and locating the  
25 fastener too far from that surface can result in failure  
to provide hemostasis and subsequent hematoma and/or  
pseudo aneurism formation. Conversely, if the fastener  
intrudes into the arterial lumen, intravascular clots  
and/or collagen pieces with thrombus attached can form  
30 and embolize downstream causing vascular occlusion.  
Also, thrombus formation on the surface of a fastener  
protruding into the lumen can cause a stenosis which can  
obstruct normal blood flow. Other possible complications  
include infection as well as adverse reactions to the  
35 collagen implant.

For these reasons, it would be desirable to  
provide improved devices and methods to seal body lumen

puncture sites. It would be particularly desirable to provide percutaneous devices and methods for suturing the puncture sites required for percutaneous vascular procedures.

## 5      **2.      Description of the Background Art**

Devices capable of delivering pairs of needles to various tissue locations are described in the following patents and patent applications: U.S. Patent Nos. 4,493,323 and 659,422; European patent application 10      140 557; and U.S.S.R patent applications 1174-036-A and 1093-329-A. Other suturing and ligating devices are described in U.S. Patent Nos. 3,665,926; 2,959,172; and 2,646,045. Devices for sealing percutaneous vascular penetrations using various fastener structures are 15      described in U.S. Patent Nos. 5,061,274; 5,021,059; 4,929,246; 4,890,612; 4,852,568; 4,744,364; 4,587,969; and 3,939,820. Collagen fastener sealing devices are under commercial development by Datascope Corp., Montvale, New Jersey, and Kensey Nash Corporation, Exton, 20      Pennsylvania.

## **SUMMARY OF THE INVENTION**

The present invention provides devices and methods for suturing percutaneous luminal puncture sites. The devices will comprise a shaft, a pair of needles 25      carried (usually removably) near the distal end of the shaft, and a length of suture secured to and extending between the needles. As described below, the shaft is used to introduce the needles inwardly through the tract and puncture site and into the lumen. Thereafter, the 30      shaft is used to draw the needles outwardly back through the tissue on either side of the puncture site to begin forming a loop of the suture at the intimal surface of the puncture site. The device may further include means on the shaft for capturing the pointed ends of the 35      needles after they have passed through the tissue and back into the tract, and the shaft can then be withdrawn to carry the needles and attached suture outwardly back

through the tract. Alternatively, the shaft and needles can be made sufficiently long so that the pointed ends of the needles may be drawn completely through the tract so that they may be manually grasped (without the need for capture on the shaft). In either case, the free ends of the suture can then be tied (or otherwise secured) and the resulting knot pushed back through the tract to complete the suture loop at the adventitial surface of the puncture site. The ability to provide a secured suture loop at the puncture site is particularly advantageous since a reliable closure is formed. Furthermore, suture closure of puncture sites has been universally accepted as the standard of care for many decades.

The devices and methods of the present invention are useful whenever it is desirable to place a tied suture loop to close a lumen puncture site, and will be particularly useful for suturing percutaneous vascular puncture sites. The devices can achieve closure wholly through the tract puncture site and can be manipulated entirely in a percutaneous manner. The present invention will find its greatest use in the sealing of femoral artery cannulation sites made in connection with percutaneous transluminal procedures, such as angiography, angioplasty, atherectomy, laser ablation, stent placement, intravascular imaging, and the like. The present invention will also find use in other medical procedures which rely on percutaneous access to hollow body organs and lumens, such as laparoscopic procedures, endoscopic procedures, artherosclerotic procedures, and the like.

In a particular embodiment, the device of the present invention comprises the shaft, pair of needles, and length of suture, generally as described above. The device further comprises a sleeve received over the shaft and having a receiving area disposed near the distal end of the shaft. The device may also include means for

expanding the receiving area and drawing the needles into the expanded receiving area, in order to capture the needles so that they may be withdrawn by the shaft through the tract. Conveniently, the expanding means may be an expandable cage and the receiving area may be defined by a fabric or mesh which will engage and entrap the needles (which are preferably barbed at their distal ends) so that they may be withdrawn by the shaft.

In a second particular aspect, the device of the present invention comprises a shaft, pair of needles, and length of suture, generally as described above, further in combination with a guide body having a proximal end, a distal end, and means for slidably receiving the flexible shaft therethrough, typically being a central lumen. The guide body further includes means at its distal end for retaining the pointed tips of the needles as the device is inserted through a percutaneous tract and puncture site and for guiding the needles in a desired pattern so that they will penetrate the arterial wall opposite each other around the puncture site. Preferably, the needles and portion of the shaft which extend beyond the distal end of the guide body are retained within a flexible sheath, with the suture being within or parallel to the sheath, which facilitates introduction of the device and helps align the needles as they are withdrawn by the shaft through the tissue. In this embodiment, the shaft and needles are sufficiently long so that the needles may be drawn outwardly through the tissue and entirely through the preexisting tract while still being held on the shaft. In this way, the pointed tips of the needles will be available so that the user can manually grasp and remove them. Alternatively, the suture may be simply removed from the needles and the needles retracted distally to disengage tissue and permit the device to be withdrawn. Securing of the suture will be accomplished as described above.

In a further aspect of the present invention, a fastener may be introduced over the free ends of the suture after they have been drawn outwardly through the percutaneous tract. The fastener is pushed into the tract to a location just superficial to the adventitial surface of the puncture site, and the fastener locked in place by rotating the fastener through at least one-half turn to cross over the two suture ends. The fastener may then be secured in place by tying the remaining free ends of the suture and pushing the resulting knot down onto the fastener.

The present invention still further provides a device for introducing the fastener just described. The fastener introducing device comprises a shaft having a proximal end and a distal end. Means at the distal end of the shaft are provided for detachably securing the fastener, and means of the proximal end of the shaft are provided for selectively detaching the fastener after it has been placed in the desired location within the percutaneous tract. The fastener includes at least two suture-receiving slots which permit the fastener to be introduced over the suture as it is introduced inwardly through the tract. After the fastener has been introduced sufficiently deep to be placed over the adventitial surface of the puncture site, the device may be used to turn the fastener prior to fastener detachment. The device is then removed and the free ends of the suture tied and the resulting knot pushed back down over the fastener to secure it in place.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

Fig. 1 is a perspective view of a suturing device constructed in accordance with the principles of the present invention.

Fig. 2 is a detailed view of the distal end of the suturing device of Fig. 1.

Fig. 3 is a cross-sectional view of the device of Figs. 1 and 2, taken along line 3-3 of Fig. 2.



Fig. 4 is a detailed view of the distal end of the sleeve element of the device of Fig. 1, shown in its non-collapsed state.

Fig. 5 is a view of the distal end of the sleeve element, similar to Fig. 4, shown in its collapsed configuration to define an enlarged receiving area.

Fig. 6 is a cross-sectional view of the proximal end of the suturing device of Fig. 1.

Fig. 7-12 illustrate use of the suturing device of Fig. 1 in applying and tying a suture loop through a percutaneous tract to a blood vessel wall.

Fig. 13 illustrates a fastener applying device constructed in accordance with the principles of the present invention.

Fig. 14 is a detailed view of the distal end of the fastener applying device of Fig. 13.

Fig. 15 is a cross-sectional view of the fastener applying device of Figs. 13 and 14, taken along line 15-15 of Fig. 14.

Figs. 16 and 17 illustrate placement of the fastener in connection with tying of the free ends of the suture and the method of the present invention.

Figs. 18 and 19 illustrate a first alternative embodiment of the fastener of the present invention.

Figs. 20 and 21 illustrate a second alternative embodiment of the fastener of the present invention.

Figs. 22 and 23 illustrate a third alternative embodiment of the fastener of the present invention.

Fig. 24 is an exploded view of a second embodiment of a suturing device constructed in accordance with the principles of the present invention.

Fig. 25 is an enlarged view of the proximal end of the suturing device of Fig. 24.

Fig. 26A is an enlarged elevational view of a portion of the proximal end of the device illustrated in Fig. 25.

Fig. 26B is a cross-sectional view taken along line 26B-26B in Fig. 26A.

Fig. 27A is a perspective view of the suturing device of Fig. 24, shown in an assembled configuration.

5 Fig. 27B is an enlarged detail view of the distal tip of the suturing device illustrated in Fig. 27A.

10 Fig. 28 illustrates the introduction of the outer sheath which forms a part of the suturing device of Fig. 24A through a percutaneous tract.

Fig. 29 illustrates placement of the remaining portions of the suturing device within the sheath, as introduced in Fig. 28.

15 Fig. 30A illustrates initial needle penetration by drawing back the needle-carrying shaft of the suturing device introduced as in Fig. 29.

Fig. 30B is a detail view showing the needle penetration of Fig. 30A.

20 Fig. 31A shows the needles after they have been captured on the shaft of the suturing device and have been partially withdrawn through the sheath.

Fig. 31B is a detail view of the distal end of the suturing device, as illustrated in Fig. 31A.

25 Fig. 32 is a perspective view from inside a blood vessel illustrating the geometry of the needle penetration afforded by the needle guide carried at the distal end of the shaft of the suturing device of the present invention.

30 Fig. 33 illustrates the X-pattern of the tied suture applied by the suturing device.

Fig. 34 is a perspective view of a second alternate embodiment of a suturing device constructed in accordance with the principles of the present invention.

35 Fig. 35A is a detail view of the distal end of the guide body of the suturing device of Fig. 34, shown with the needles retracted fully within the guide body.

Fig. 35B is a view similar to Fig. 35A, except that the needles have been partially drawn back into the guide body.

Fig. 36 is a cross-sectional view of the device of Figs. 35A and 35B, taken along line 36-36 of Fig. 35B.

Figs. 37-40 illustrate the method of the present invention using the suturing device of Fig. 34.

#### **DESCRIPTION OF SPECIFIC EMBODIMENTS**

Referring to Figs. 1-3, a suture applying device 10 which is suitable for suturing and sealing of percutaneous vascular puncture site, particularly those made to the femoral artery in a patient's groin, will be described. It will be appreciated, however, that the device of the present invention can be readily adapted for use with punctures made to other hollow body organs and lumens, although it may be necessary to modify the dimensions and other particular aspects of the device to accommodate the different usage environment.

The device 10 of the present invention comprises an elongate body which includes an outer sleeve 12 and inner shaft 14. The shaft 14 is slidably positioned within the sleeve 12, with the sleeve and shaft being interconnected by a proximal actuator assembly 16 (best illustrated in Fig. 6). The inner shaft 14 will be hollow, defining a guidewire lumen (not illustrated) extending from the proximal actuator assembly 16 to the distal tip 18 of the device 10. In this way, the device 10 can be introduced over a conventional guidewire GW to facilitate introduction and manipulation of the device throughout the procedure, as described in detail hereinafter. The suture applying device 10 will be introduced through a conventional introducer sheath S, shown in phantom in Fig. 1. The ability to introduce the device 10 over the guidewire is not essential to the present invention, but will generally be preferred since most physicians desire that intravascular devices be manipulated over a guidewire.

Introduction through the introducer sheath optionally provides containment of the suture as they are being introduced, as discussed hereinafter.

Referring in particular to Figs. 2 and 3,  
5 suture needles 20 are carried in the suture retainer 22 which is mounted on the distal end of shaft 14. The suture retainer 22 includes a pair of slots 24 which serve as receptacles for the proximal shank portions 26 of each needle 20. The shank portions 26 will be shaped  
10 to mate with the slots 24 so that the needles 20 are maintained in a desired orientation. Preferably, the needles 20 include arcuate portions proximal to the tip which first extend radially outward from the shaft 14 but then turn back radially inward toward the shaft over  
15 their proximalmost portions. As described in greater detail hereinafter, this arcuate shape is desirable since it helps direct the needles 20 through a path in the tissue which brings them back into the shaft 14, where they can be captured by a capturing assembly which is  
20 described hereinafter.

Preferably, the needles will be composed of a highly resilient surgical metal, such as certain nickel titanium alloys, such as Nitinol®. The use of such resilient alloys permits the needles to be compressed  
25 radially inward as the device 10 is introduced through the introducer sheath S. The needles 20 will spring back to their original shape, as illustrated in Figs. 1 and 2, as soon as they pass from the distal end of the sheath S.

This ability to open or spread the needles 20  
30 after they have been introduced through the introducer sheath S is important to the present invention since it is necessary to deploy the needles on either side of the percutaneous penetration. Such deployment of the needles could, of course, be achieved by a variety of mechanical  
35 mechanisms which would positively act on the needles to deflect them outwardly in the desired orientation. The use of inherently resilient springs, however, greatly

simplifies the design of the device since no movable mechanical components are required to achieve the desired spreading of the needles 20.

The needle shanks 26 will typically be formed of stiffer material, such as stainless steel, to provide a strong base for retention within the needle retainer 22. Conveniently, the shanks may be formed from stainless steel hypodermic tubing which can be placed over and affixed to the butts of the needles 20 and flattened into a desired shape. The slots 24 can then be oriented to receive the flattened shanks 26 and hold the needles 20 in their preferred configuration as illustrated in Fig. 2.

The needles 20 are joined by a length of suture which is secured to the shank end 26 of each needle and extends therebetween. Conveniently, the suture 30 will be coiled between the shaft 14 and each needle shank 26, as best illustrated in Fig. 3. The suture should be stored on the device so that it is readily left behind in the body lumen as the device 10 is withdrawn through a percutaneous penetration, as described in greater detail hereinafter. To that end, it is desirable that the needle retainer 22 be smoothly shaped so that the suture can easily pass thereover as the device 10 is withdrawn.

Referring now also to Figs. 4 and 5, the device 10 will carry a structure for capturing the needles 20 after they have been drawn through the tissue on either side of the percutaneous penetration. The structure may take a variety of forms, conveniently comprising a fabric or mesh surface 32 which defines an expandable receiving area for the needles. The needles 20 may include barbs 40 (Fig. 2) formed at or near their tips, and the barbs will be entrapped by the fabric or mesh surface 32 after they penetrate therethrough.

While it would be possible to provide a fixed receiving area, i.e. non-expandable, it will usually be preferable to provide a mechanism for expanding and

orienting the receiving area to aid in capturing the needles 20. A variety of suitable expandable support structures could be provided, with the exemplary support structure being formed integrally as an expandable cage in the distal end of sleeve 12. The expandable cage includes a plurality of axial ribs 42 having hinged regions 44 so that the ribs may be expanded radially outward by compressing the sleeve 12 against a stop member 46 (mounted on the shaft 14 as best seen in Fig. 2), as will be described in more detail hereinafter.

In a preferred aspect of the present invention, the hinged regions 44 on axial ribs 42 of the cage structure on sleeve 12 will be unevenly axially spaced. By providing both symmetric hinge location, i.e. located in the middle of the rib, as well as asymmetric hinge location, the resulting asymmetric shape of the expandable cage will present a wider target of open windows for incoming needles 20. In this way, efficient capture of the barbed ends 40 of the needles 20 can be achieved.

Referring now in particular to Fig. 6, the proximal actuating assembly 16 includes a housing base 50 which is attached to the proximal end of sleeve 12 and a housing cap 52 which is secured to the housing base. The shaft 14 passes through an open interior 54 of the housing cap 52 and passes proximally outward through an aperture 56. A handle 58 is attached to the proximal end of the shaft 14 and permits a user to axially translate the shaft 14 relative to the sleeve 12. A compression spring 60 is mounted within the opening interior 54 of the housing cap 52 and acts against a piston element 62 which is fixedly secured to the shaft 14. The piston element 62 is located so that it lies against a distal travel stop 64 formed in the housing base 50 when the shaft 14 is disposed at the distal limit of its travel, as illustrated in Fig. 7.

The handle 58 can be used to draw the shaft 14 in the proximal axial direction until the piston element 62 engages an annular proximal travel stop 66 formed within the housing cap 52, as illustrated in broken line in Fig. 6. With the shaft 14 thus in its most proximal position, the cage structure will have been expanded and the needles 20 drawn into the receiving area, as illustrated in Fig. 9 and discussed in more detail hereinafter.

Referring now to Figs. 7-12, use of the device 10 in applying and tying a suture loop in a blood vessel wall will be described in more detail. Referring in particular to Fig. 7, the device 10 is introduced through an introducer sheath S which may have been previously placed in connection with a conventional intravascular diagnostic or treatment protocol, such as angiography, angioplasty, atherectomy, laser ablation, cardiac mapping, cardiac ablation, or the like. The device 10 is introduced with the needles 20 compressed radially inward so that they will fit within the internal diameter of the sheath S. A particular advantage of the device 10 is that it can be introduced over the guidewire GW which has been used for performing the previous procedures. Thus, should it be necessary for any reason, the guidewire GW will remain in place until the very end of the suturing procedure.

As illustrated in Fig. 8, after the distal end of the device 10 including the needles 20 has reached the lumen of the blood vessel BV, the introducer sheath S will be partially withdrawn, permitting the resilient needles 20 to open radially outward so that the barbed tips 40 are disposed on opposite sides of the blood vessel wall tract P.

The user next draws proximally on the handle 58, causing the shaft 14 to move proximally relative to the sleeve 12. Proximal motion of the shaft 14, in turn, causes the needles 20 to penetrate through the blood

vessel wall BV, with the arcuate shape of the needles causing the needles to move radially inward back toward the shaft 14. Continued proximal travel of the shaft 14 causes the stop member 46 to engage the distal end 70 of the sleeve member 12. Continued proximal travel of the shaft 14 thus causes axial compression of the sleeve 12, expanding individual ribs 42, as described above. The relative positions of the ribs 42 and needles 20 are chosen so that the expandable cage opens into the needles' path as they are brought backward through the blood vessel wall BV and surrounding tissue. The barbed ends 40 of the needles 20 are thus able to penetrate the fabric or mesh 32 carried on the expandable cage to engage and secure the needles. The situation where the needles have been secured is illustrated in Fig. 9.

After the needles 20 are captured, the handle 58 is released, causing the shaft 14 to distally advance under the urging compression spring 60. Such distal motion of the shaft 14 causes the needle retainer 22 to move away from the needles 20 which are held by the fabric or mesh 32 on the expandable cage structure, as illustrated in Fig. 10.

The device 10 may be drawn outward through the introducer sheath S, leaving the suture 30 behind (passing through the two needle penetrations made in the blood vessel wall BV and overlying tissue). The free ends of the suture 30 will thus be drawn outward through the percutaneous tract P, as illustrated in Fig. 11.)

At this point, it will be possible to secure the free ends of the suture together, e.g., by tying to form a knot 72 which can be pushed downward using a pusher rod 74, as illustrated in Fig. 12. The introducer sheath may be removed either before or after the knot 72 is put in place. As an alternative to tying, various fasteners can be used to secure the free ends of the suture together, either alone or in combination with knotting.



In a preferred option of the present invention, a locking fastener 80 may be inserted over the free ends of the suture 30 using a fastener applier 82, as illustrated in Fig. 13. The locking fastener 80, in combination with a tied suture loop, provides a particularly secure barrier against bleeding, without having the disadvantages of the hemostatic fasteners which have previously been used.

The fastener applier 82 comprises a shaft 84 including a pair of axial prongs 85 and an axial rod 86. As best illustrated in Figs. 14 and 15, the axial prongs 85 terminate in outwardly disposed tips 88 which are received in receptacle wells 90 formed in a rear surface 89 of the locking fastener 80. The axial prongs 85 are resilient and tend to spring radially outward, thus allowing the tips 88 to hold the fastener member 80 by engaging the well receptacles 88. The locking fastener 80 can be placed over the ends of suture 30 through slots 92 formed on opposite sides of the fastener.

Referring now to Figs. 16 and 17, after the suture 30 has been drawn out through the tract P and introducer sheath S, fastener 80 is introduced over the suture 30 using the applier 82. Once the fastener 80 is positioned a proper distance over the blood vessel BV, as illustrated in Fig. 17, the suture applier will be rotated to twist the suture, as shown at 96. A knot 98 may then be tied in the remaining free ends of the suture 30 and pushed downward over the fastener 80 to secure the fastener in place.

Alternate locking fastener embodiments are illustrated in Figs. 18-23. In Figs. 18 and 19, a locking fastener 100 includes a cylindrical cavity 102 which would permit the fastener to be placed closely over the blood vessel. In Figs. 20 and 21, the fastener 104 includes a concave hemispherical recess 106 which would also permit close placement of the fastener over a blood vessel wall. Finally, in Figs. 22 and 23, fastener 108

includes a flat face 110 which would also be suitable for use in the present invention.

In addition to tying and use of a fastener, the present invention will encompass other devices and approaches for securing the suture as will be readily apparent to one skilled in the art.

Referring now to Figs. 24-27, a second embodiment of the suture applying device of the present invention will be described. Suture applying device 200 comprises an introducer sheath 202, a support sheath 204, a capture sleeve 206, a guide sleeve 208, and a needle shaft 210. The capture sleeve 206 will be mounted coaxially over the guide sleeve 208, and the guide sleeve 208 in turn will be mounted coaxially over the needle shaft 210, in order to form a needle advance and capture assembly 212, as illustrated in Figs. 27A and 27B. The introducer sheath 202 will initially be mounted within the support sheath 204 in order to facilitate introduction of the support sheath into a previously formed percutaneous tract, with only the thinner tip 280 of the introducer projecting into the arteriotomy and the shoulder 281 stopping at or near the superficial wall of the artery. After introduction of the support sheath 204, the introducer sheath 202 will be removed, and the needle advance and capture assembly 212 will be introduced through a lumen of the support sheath, as will be described in more detail hereinafter.

Referring now to Figs. 24 and 27B, the needle holder 210 comprises an elongate rod 220 having a needle support holster 222 at a distal end thereof and a knob 224 at a proximal end thereof. The needle support holster 222 carries at least one pair of opposed needles 226, usually carrying two pair of opposed needles as illustrated. As best observed in Fig. 27B, the needles 226 will initially be held at their proximal ends in the support holster 222 with their distal ends being positioned in a guide member 228 secured to the distal

end of the guide sleeve 208. It will be appreciated that the needles 226 can thus be advanced proximally (i.e., in an upward direction as illustrated in Fig. 27B) by drawing the needle shaft 210 proximally relative to the guide sleeve 208.

The guide member 228 includes a plurality of guide channels or lumens 230 for receiving the needles 226. The guide channels 230 will be oriented so that the needles 226 are deflected radially outward relative to the needle advance and capture assembly 212 as the needles are advanced proximally relative to the guide sleeve 208. Such radial deflection assures that the needles will penetrate tissue away from the arteriotomy, as best observed in Fig. 30B, described hereinafter.

The needles 226 will typically be formed of a very resilient metal, which will allow the needles to negotiate the relatively sharp bend leading into the arterial lumen of the femoral artery FA, as best seen in Fig. 29. In particular, the needles will be configured in a straight shape but will be able to bend into a slightly arcuate path after crossing the tissue to be sutured and then being deflected inwardly back into the lumen of support sheath 204 by a ridge 239 on the inner wall of support sheath 204, where they will be captured on the capture sleeve 206, as described in more detail hereinafter. A preferred material for fabricating the needles is a nickel-titanium alloy in its superelastic condition, but a high tensile strength stainless steel may also be used.

The capture sleeve 208 comprises a cylindrical body 234 having a central lumen extending from an open distal aperture 236 to a proximal handle 238. The guide sleeve 208 will be slidably received within the lumen of the capture sleeve 206, with the guide member 228 extending out of the open distal aperture 236, as best observed in Figs. 27A and 27B. The capture sleeve 206 includes a capture target 240 which is conveniently an

annular disk secured to the exterior of the sleeve. The capture target 240 may be composed of any material which is easily penetrable by the needles 226 and which can serve to capture the distal ends of the needles so that they may be drawn outwardly by the target as the capture sleeve 206 is pulled via handle 238 so as to disengage needles 226 from support holster 222 and pull needles 226 through guide member 228 and clear of arterial tissue of the femoral artery FA surrounding the puncture site and into the lumen of support sheath 204 as described hereinafter. A second annular disk 242 is provided on the sleeve 206 proximally of the capture target 240, to assist in centering capture sleeve 206 within support sheath 204. Suitable materials for these components include nylon, delrin, polycarbonate, and other moldable or extrudable materials.

Referring now also to Figs. 25, 26A, and 26B, the proximal end of guide sleeve 208 includes a cage structure 250 having an H-frame which comprises parallel axial tracks 252, a top bar 254, and a middle bar 256. An elliptical or oblong ring 258 is part of the distal ends of the parallel tracks 252 in such a way that the tracks can be spread apart (as illustrated in Fig. 26A) with the ring acting as a spring. Conveniently, the user may spread the tracks 252 apart by compressing the elliptical ring 258 along the longer elliptical axis. The inner surfaces of the distal portions of parallel tracks 252 comprise gear teeth 260 which mate with gear teeth 262 on a proximal end of the support sheath 204. It will be appreciated that the gear teeth 260 and 262 will mesh to hold guide sleeve 208 in a fixed position relative to the support sheath 204 at all times except when the parallel tracks 252 are spread apart by compressing the elliptical ring 258. As described in more detail hereinafter, this feature allows the user to introduce the needle advance and capture assembly 212 to a desired depth relative to the support sheath 204 and

thereafter leave the assembly at the desired position until it is time to remove the entire capture assembly 212.

Prior to use, the needle advance and capture assembly 212 will be in the configuration illustrated in Figs. 25, 27A and 27B. That is, the needle shaft 210 will be in its most distal position relative to the guide sleeve 208. Knob 224 attached to needle shaft 210 will lie adjacent the middle bar 256 of the cage structure 250. The capture sleeve 206 will lie in its most proximal position relative to the guide sleeve 208, with knob 238 lying adjacent the elliptical ring 258. In use, it will be appreciated that the needle shaft 210 will first be drawn proximally via the handle 224 in order to pass the needles 226 through the site to be sutured, and into engagement with the capture target 240 which is an integral part of capture sleeve 206 to effect capture of needles 226. Such a method will now be described in greater detail in connection with Figs. 28-33.

The method of utilizing device 200 begins by inserting the support sheath 204 having introducer sheath 202 in place within its central lumen. The introducer sheath 202 defines a tapered end 280 which may be introduced over a guidewire 282 which has previously been placed in the percutaneous tract P and the puncture site A through the femoral artery FA as part of an earlier procedure. A proximal end 284 of the introducer sheath 202 extends outward from the proximal end of the support sheath 204, and the introducer sheath will be composed of a resilient material which allows the introducer sheath to be collapsed and withdrawn from the support sheath after the support sheath is properly positioned. Conveniently, the distal end of the support sheath 204 will have a serrated edge in order to help anchor the support sheath in place within the tract P and centered around the puncture site. As illustrated in Fig. 28, the support sheath 204 includes a manipulation knob 286

having a pointer 288 near its proximal end. The manipulation knob 286 allows the user to manipulate the combination of support sheath 204 and introducer sheath 202 as they are being positioned within the tract P. The pointer 288 will be oriented in a predetermined direction relative to the patient in order to facilitate positioning following the remaining steps of the method. Typically, the pointer 288 will be oriented toward the patient's head in a conventional cardiac interventional procedure accessed through a femoral arteriotomy.

Referring now to Fig. 29, the needle advance and capture assembly 212 will be introduced to the support sheath 204 after the introducer sheath 202 has been withdrawn. The assembly 212 will be inserted into the support sheath 204 until the guide member 228 on the guide sleeve 208 enters the lumen of the femoral artery FA through the arteriotomy A. To assist the user in determining when the guide member has entered the femoral artery FA, a blood inlet port 290 (best observed in Figs. 24 and 30) is provided near the distal end of the guide sleeve 208. Port 290 is connected to a viewing port 292 through a lumen 294 (Fig. 26B). The viewing port 292 incorporates a small vent (not shown) so that air may easily be expelled from the lumen 294 to permit blood flow to reach the viewing port, but is sufficiently small to restrict the outward flow of blood from the viewing port. Thus, the user will be able to see blood appear at the viewing port 292 as soon as the guide member 228 has entered the femoral artery FA. At that point, the user can stop insertion. The assembly 212 will be held in place relative to the support sheath 204 through the meshing of teeth 260 and 262 as described previously.

With the needle advance and capture assembly 212 being fully introduced through the support sheath 204, the needles 226 will be fully introduced into the femoral artery FA. In particular, the tips of the

needles will lie on the superficial side of the arteriotomy in the artery wall.

Referring now to Fig. 30A and 30B, the needles 226 will be drawn proximally through the wall of femoral artery FA by pulling knob 224 in a proximal direction relative to the remainder of the device, as illustrated by arrow 300 in Fig. 30A. The knob 224 will draw the needle shaft 210 in the proximal direction which in turn causes the needle support holster 222 to push the needles in the direction of arrows 302 and 304. The needle guide member 228 causes the needles 226 to flare radially outward so that they pass through the blood vessel wall, and into engagement with the capture target 240 within the lumen of the support sheath 204 as illustrated in Fig. 30B.

The suture 310 (Fig. 31B) carried between adjacent pairs of needles 226 will then be drawn downward through the support sheath 204, through the gap between the arteriotomy A in the femoral artery FA and the guide sleeve 208, through the punctures left by needles 226, and finally out through the lumen of the support sheath as the needles are first moved partly outward by the action of knob 234, and then carried outward by the target 240 with the removal of the entire capture assembly 212 from support sheath 204.

Referring now to Fig. 32, the preferred pattern of four needles being delivered by the needle support holster 222, through the needle guide member 228, and into the wall of the femoral artery FA is illustrated. It can be seen that the guide member 228 deflects the needles radially outward so that the pattern of four needles engages the artery wall in an approximately square pattern about the arteriotomy A. After the sutures are tied and the knots advanced back through the support sheath 204, the resulting pattern of tied suture will appear as in Fig. 33 when viewed towards adventitial

surface of the femoral artery FA surrounding the arteriotomy A.

5 A third embodiment of the suture applying device of the present invention is illustrated in Figs. 34-36. The device 400 comprises a guide body 402 and a needle shaft 404. The guide body 402 includes a guide tip 406 at its distal end, which guide tip includes a plurality of guide channels 408 which receive the proximal ends of needles 410. A tissue-receiving region or "gap" is created between the proximal ends of the guide channels 408 and the distal end of the guide body 402 (which includes needle receiving lumens 420 described hereinafter), and the guide channels will thus direct the needles through desired target locations on opposite sides of the blood vessel wall puncture. An aligning arrow 403 is mounted on handle 405 located at the proximal end of the guide body 402. A marker lumen bubble 407 is located below the aligning arrow and serves to indicate when the distal end of the guide body has entered a blood vessel, as described in connection with previous embodiments. An indicator lumen 411 which permits the flow of blood to the marker lumen bubble 407 is illustrated in Figs. 35A and 35B.

25 The needles 410 as illustrated comprise a sharpened tip section 412 and an elongate shank portion 414, but may also be manufactured as an integral piece. The shank portion 414 will be sufficiently long so that the needles may be pushed from their butt end by a support holster 428 fixedly attached to the needle shaft 404 in order to advance the needles through the tissue to be sutured and fully through the guide body 402 inserted together with support sheath 440 in the associated tract so that no capture mechanism will be required, as with previous embodiments.

35 The guide body 402 further includes a plurality of needle lumens 420 which are axially aligned and spaced about the periphery of the guide body. As best seen in



Fig. 35B, the needles 410 will enter the distal ends of the lumens 420 as the needles are advanced proximally relative to the guide body.

A flexible needle sheath 426 will be attached to the guide tip 406 of guide body 402. The central lumen of the needle sheath 426 receives a support holster 428 attached to the distal end of the needle shaft 404, as well as the needles 410. As with previous embodiments, the butts of the needles 410 are removably received within the support holster 428. The sheath 426 will be sufficiently long to permit the needles to extend at least 5 cm beyond the distal end of guide body 402.

Prior to use, the suture applying device 400 will be in the configuration illustrated in Figs. 34 and 35A. That is, the needle shaft 404 will be distally positioned within the guide body 402 and needle sheath 426. In particular, the tips of needles 412 will lie just at the guide tip 406 so that they may be easily advanced through the arterial tissue surrounding the arteriotomy. That is, the tips of the needles will be generally retracted within the guide tip 406. A length of suture 422 is attached to the proximal tips 412 of opposed pairs of needles 410, with the connecting suture being stored in side lumens 427 extending axially along the exterior of the needle sheath 426. As best observed in Figs. 35A and 35B, the suture 422 extending between one pair of opposed needles is received in a first of the side lumens 427, while the suture extending between the other pair of opposed needles is received in the second of the side lumens. While it would be possible to store the suture 422 in the lumens 420 of the guide body 402 (and thus eliminate the need for side lumens 427), such storage is less preferred since it increases the risk that the suture will become entangled with the needles 410 as they are withdrawn proximally. The use of side lumens 427 greatly simplifies feeding of the suture as the needles 410 are withdrawn.

After the guide tip 406 has been passed through the puncture site to be sutured, the needles may then be drawn proximally forward through the tissue to be sutured by drawing proximally on handle 430 at the proximal end of needle shaft 404. The method of the present invention will now be described in more detail with reference to Figs. 37-41.

The situation following an interventional or other vascular procedure, where the attending physician is satisfied that the puncture site may be sealed, is illustrated in Fig. 37. A conventional introducer sheath is in place with a guidewire passing into the femoral artery. The conventional introducer sheath is withdrawn after assuring that an appropriate guidewire for the suturing process is in place. The device 400 (including a support sheath 440 which initially covers the ports to the needle lumens 420) will then be introduced over the guidewire, as illustrated in Fig. 37. The needles 410 and sutures 422 encased by flexible needle sheath 426, will be fully advanced into the femoral artery FA past the arterial puncture site A. Handle 441 on support sheath 440 is then partially withdrawn proximally to expose the needle lumens 420 (as shown in Figs. 35A, 35B, and 38. Handle 430 will then be drawn proximally outward relative to the guide body 402, causing the needles 410 to pass through the superficial wall of the femoral artery FA and into the needle lumens 420, as illustrated in Figs 35B and 38. The handle 430 may continue to be drawn proximally (i.e., outward from the patient) in order to continue to pull the needle shaft 404 through the guide body 402. Such movement of the needle shaft 404, in turn, continues to draw the needles 410 outward through the lumens 420 of the guide body 402 until the tips of the needles are exposed. The user may then grasp the needles and continue to draw them out until the suture is available to the user. Alternatively, the user may detach the free ends of the suture from the needles,

and push handle 430 and shaft 404 back into the guide body to return the needles 410 back into the sheath so that the needles disengage the tissue. The guide body 402 may then be withdrawn from the support sheath 440, leaving a portion of the needle sheath 426 still in the puncture site A to maintain hemostasis. The suture can then be tied and the knot pushed back down through the support sheath 440. The knot will then only be tightened when the needle sheath is finally withdrawn from the puncture site A.

Device 400 has certain advantages over the previous embodiments. Since it is not necessary to capture the needles using an internal capture mechanism, the needles need not have barbs. Such barbless needles will minimize trauma to the arterial tissue around the puncture site A and simplify the procedure. The guide body 402 and guide tip 406 are designed as an integral structure to assure that needles 410 will be precisely centered around the puncture site A, and will very reliably enter the needle lumens 420 in guide body 402. Also, tip 406 will occlude the arteriotomy puncture during the performance of the procedure, providing hemostasis. Moreover, the entire procedure is simplified, with fewer discrete steps being performed. The user need only introduce the device over-the-wire and thereafter draw out the needle shaft to carry the needles through the tissue to be sutured and outward through the guide body, where the suture becomes accessible and may be tied in a conventional manner. Additionally, by appropriately sizing the needle sheath 426, hemostasis can be maintained during all or most of the procedure. Typically, the needle sheath 426 may be sized to have the same diameter as a guiding catheter so that it will substantially occlude the arteriotomy when in place. Moreover, the extended length of the needle sheath 426 allows it to maintain hemostasis even when the device is

partially withdrawn, e.g. when the suture is being tied or secured by a fastener.

5           Although the foregoing invention has been described in detail for purposes of clarity of understanding, it will be obvious that certain modifications may be practiced within the scope of the appended claims.

WHAT IS CLAIMED IS:

1                   1.    A suturing device comprising:  
2                   a guide body having a proximal end and a distal  
3                   end;  
4                   a shaft having a proximal end and a distal end,  
5                   said shaft being slidably mounted in the guide body;  
6                   a pair of needles removably carried near the  
7                   distal end of the shaft, wherein each needle includes a  
8                   shank and a sharpened tip with the shank carried on the  
9                   shaft and the tip disposed toward the proximal end of the  
10                  shaft;  
11                  a length of suture secured to and extending  
12                  between the needles;  
13                  means on the guide body for receiving the  
14                  needles and passing said needles to the proximal end of  
15                  the guide body as said needles are drawn proximally by  
16                  said shaft; and  
17                  means near the distal end of the guide body for  
18                  guiding the needles through tissue and to the needle  
19                  receiving means as said needles are drawn proximally by  
20                  said shaft.

1                   2.    A suturing device as in claim 1, wherein  
2                   the shaft and the needles are flexible and at least as  
3                   long as the guide body.

1                   3.    A suturing device as in claim 2, wherein  
2                   the means for guiding the needles comprises a guide tip  
3                   fixed at the distal end of the guide body and having  
4                   guide channels for receiving the flexible needles.

1                   4.    A suturing device as in claim 3, further  
2                   comprising a flexible sheath attached to and extending  
3                   distally from the guide tip, wherein said sheath receives  
4                   the flexible needles and shaft prior to the needles and  
5                   shaft being drawn proximally into the guide body.

1                   5. A suturing device as in claim 2, wherein  
2 the means for receiving comprises axial lumens formed in  
3 the guide body which receive the needles as the shaft is  
4 drawn proximally.

1                   6. A suturing device as in claim 5, wherein  
2 the shaft is slidably received in an axial lumen of the  
3 guide body.

1                   7. A suturing device as in claim 1, wherein  
2 the needles each have arcuate ends near the tips.

1                   8. A suturing device comprising:  
2 a shaft having a proximal end and a distal end;  
3 a pair of needles removably carried near the  
4 distal end of the shaft;  
5 a length of suture secured to and extending  
6 between the needles;  
7 a sleeve received over the shaft; and  
8 means disposed on the sleeve for presenting a  
9 receiving area to the needles as the shaft is drawn  
10 proximally relative to the sleeve, whereby the needles  
11 may be captured in the receiving area after they have  
12 passed through tissue.

1                   9. A suturing device as in claim 8, wherein  
2 the receiving area is a fabric or mesh which is carried  
3 on an expandable cage structure disposed between the  
4 distal end of the sleeve and the distal end of the shaft,  
5 whereby the cage is expanded radially outward as it is  
6 compressed by proximal movement of the shaft relative to  
7 the sleeve.

1                   10. A suturing device as in claim 9, further  
2 comprising a stop member on the shaft and means at the  
3 proximal end of the shaft for axially translating the  
4 shaft relative to the sleeve, whereby the shaft can be

5 pulled proximally relative to the sleeve to draw the  
6 needles proximally through tissue, and the cage structure  
7 expanded by engaging and compressing the stop member  
8 against the sleeve.

1 11. A suture device as in claim 10, wherein  
2 the means for axially translating the shaft comprises a  
3 handle attached to the proximal end of the shaft and a  
4 compression spring disposed between the shaft and sleeve  
5 to urge the sleeve distally relative to the shaft.

1 12. A suturing device as in claim 8, wherein  
2 the receiving area is a penetrable target carried on the  
3 sleeve.

1 13. A suturing device as in claim 8, wherein  
2 the needles each have arcuate ends near the tips and are  
3 carried on the shaft at their butts, with the arcuate  
4 ends being disposed toward the receiving area.

1 14. A suturing device as in claim 13, wherein  
2 the expandable receiving area comprises a fabric or mesh  
3 surface or a penetrable target and wherein the needles  
4 comprise a barb formed near their tips, wherein the barb  
5 will penetrate and be captured by the receiving area.

1 15. A suturing device as in claim 14, wherein  
2 the means for expanding the receiving area comprises an  
3 expandable cage structure formed in the sleeve.

1 16. A suture device as in claim 8, wherein the  
2 needles are resiliently carried on the shaft, whereby the  
3 needles can be compressed relative to the shaft as the  
4 shaft is introduced through an introducer sheath and will  
5 expand radially outwardly as the needles pass out of the  
6 introducer sheath.

1                   17. A suturing device comprising:  
2                   a flexible shaft having a proximal end and a  
3                   distal end;  
4                   a pair of needles carried near the distal end  
5                   of the shaft, wherein each needle includes a shank  
6                   carried near the distal end of the shaft and a sharpened  
7                   tip disposed toward the proximal end of the shaft;  
8                   a length of suture extending between and  
9                   secured near the tips of needles; and  
10                  a guide body having a proximal end, a distal  
11                  end, means for slidably receiving the flexible shaft,  
12                  means fixed near the distal end of the guide body for  
13                  guiding the needles as the shaft is drawn proximally  
14                  relative to the guide body, and means proximal of the  
15                  guiding means on the guide body for receiving the needles  
16                  and passing the needles to the proximal end of the guide  
17                  body as the shaft is drawn proximally relative to the  
18                  guide body;  
19                  whereby the flexible shaft may be introduced  
20                  through a tissue tract and puncture site, advanced so  
21                  that the sharpened needle tips pass beyond said puncture  
22                  site, and the shaft then drawn proximally relative to the  
23                  guide body so that the needles pass proximally through  
24                  the tissue on either side of the puncture site.

1                   18. A suturing device as in claim 17, wherein  
2                   the guide body is a tubular structure having a central  
3                   lumen which receives the flexible shaft and wherein the  
4                   needle receiving means comprises two transversely offset  
5                   axial lumens for receiving the pair of needles,  
6                   respectively.

1                   19. A suturing device as in claim 18, wherein  
2                   the tubular structure has an additional lumen which  
3                   permits the detection of blood when the distal end of the  
4                   guide body enters a blood vessel.



1                   20. A suturing device as in claim 18, further  
2 comprising a flexible sheath attached to and extending  
3 distally from the distal end of the guide body, wherein  
4 said sheath receives the shaft and needles prior to the  
5 shaft being drawn proximally and the needles drawn into  
6 the guide body.

1                   21. A suturing device as in claim 20, wherein  
2 the flexible sheath includes at least one axial side  
3 lumen for receiving suture.

1                   22. A suturing device as in claim 18, wherein  
2 the guide body has a guide tip at its distal end, wherein  
3 the guide tip includes channels which receive the distal  
4 ends of the needles and which direct the needles toward  
5 the transversely offset lumens as the shaft is drawn  
6 proximally.

1                   23. A suturing device as in claim 17, wherein  
2 the needles are carried in a support holster near the  
3 distal end of the shaft, and wherein the support holster  
4 extends distally of the distal end of the guide body by  
5 at least 5 cm prior to the shaft being drawn proximally.

1                   24. A method for suturing a puncture site in a  
2 lumenal wall distal to a tissue tract, said method  
3 comprising:

4                   introducing a pair of needles inwardly through  
5 the tract and puncture site, said needles having a length  
6 of suture extending therebetween;

7                   drawing the needles simultaneously outwardly on  
8 opposite sides of the puncture site through the lumenal  
9 wall into the tissue tract;

10                  fastening free ends of the suture to form a  
11 loop; and

12                  securing the loop to complete the suture.

1                   25. A method as in claim 24, wherein the  
2                   needles are introduced inwardly and withdrawn outwardly  
3                   using a single shaft having a proximal end and a distal  
4                   end.

1                   26. A method as in claim 25, wherein the  
2                   needles each have sharpened tips and are held at their  
3                   butts near the distal end of the shaft while they are  
4                   introduced, with the sharpened tips oriented toward the  
5                   proximal end of the shaft.

1                   27. A method as in claim 26, wherein the  
2                   single shaft is introduced through the puncture site  
3                   sufficiently far so that the sharpened tips of the  
4                   needles pass the puncture site and the shaft is then  
5                   withdrawn outwardly to pass the sharpened tips of the  
6                   needles through the tissue surrounding the puncture site.

1                   28. A method as in claim 27, wherein the  
2                   sharpened tips of the needles are captured on the single  
3                   shaft as they are drawn outwardly through the tissue  
4                   surrounding the puncture site and back into the tract.

1                   29. A method as in claim 27, wherein the butts  
2                   of the needles remain on the shaft until the tips of the  
3                   needles pass entirely through the tract and guide body,  
4                   allowing the ends of the needles nearest their tips to be  
5                   manually grasped by a user.

1                   30. A method for suturing a puncture site,  
2                   said method comprising:  
3                   introducing a shaft inwardly through the  
4                   puncture site;  
5                   positioning a pair of needles having a length  
6                   of suture therebetween carried by the shaft so that they  
7                   engage tissue on opposite sides of the puncture site;

8 drawing the shaft outwardly through the  
9 puncture site to simultaneously push free ends of the  
10 needles through the tissue;

11 guiding the needles through the tissue and  
12 outward through the puncture site so that the free ends  
13 of the needles emerge through the puncture site while  
14 proximal ends of the needles remain on the shaft;

15 pulling the free ends of the needle to remove  
16 the needles from the shaft;

17 withdrawing the shaft and the needles from the  
18 puncture site and tract to expose free ends of the  
19 suture; and

20 securing free ends of the suture to close the  
21 puncture site.

1 31. A method as in claim 30, wherein the  
2 puncture site is a percutaneous penetration to a blood  
3 vessel lumen through a tissue tract.

1 32. A method as in claim 31, wherein  
2 introducing the shaft comprises introducing the shaft to  
3 the blood vessel lumen through an introducer sheath.

1 33. A method as in claim 30, wherein the  
2 needles are compressed radially inward against the shaft  
3 as the needles are introduced through the introducer  
4 sheath and wherein the needles resiliently open as the  
5 sheath is withdrawn, whereby they are positioned to  
6 engage tissue on opposite sides of the puncture site.

1 34. A method as in claim 33, wherein the  
2 needles each have arcuate ends near their tips which are  
3 disposed radially curved inward toward the shaft, whereby  
4 drawing the shaft outwardly causes the needles to follow  
5 a radially inward path through the tissue back to the  
6 tract.

1                   35. A method as in claim 34, wherein the free  
2 ends of the needles are captured in a fabric or mesh  
3 receiving area on the shaft.

1                   36. A method as in claim 35, wherein the  
2 receiving area is expanded as the shaft is withdrawn.

1                   37. A method as in claim 36, wherein the  
2 captured needles are withdrawn with the shaft through the  
3 introducer sheath.

1                   38. A method as in claim 32, wherein the  
2 needles are guided radially inward by a guide body which  
3 extends over a proximal portion of the shaft as the shaft  
4 is introduced through the tract or puncture site.

1                   39. A method as in claim 38, wherein the shaft  
2 is introduced until a distal end of the guide body lies  
3 within the blood vessel with the needles positioned to  
4 pass through the tissue on opposite sides of the puncture  
5 site.

1                   40. A method as in claim 39, wherein the tips  
2 of the needles are captured manually.

1                   41. A method as in claim 30, wherein the free  
2 ends of the suture are secured by tying into a knot.

1                   42. A method as in claim 41, wherein the free  
2 ends of the suture are secured by introducing a fastener  
3 over the free ends of the suture.

1                   43. A fastener introducing device comprising:  
2 a fastener having at least two suture-receiving  
3 slots;  
4 a shaft having a proximal end and a distal end;

5 means at the distal end of the shaft for  
6 detachably securing the fastener; and

7 means at the proximal end of the shaft for  
8 selectively detaching the fastener;

9 whereby two ends of a length of suture  
10 extending from a percutaneous tract may be inserted into  
11 the suture-receiving slots, the fastener introduced into  
12 the penetration using the shaft, and the fastener  
13 detached at a preselected location in the tract.

1 44. A device as in claim 43, wherein the  
2 fastener includes a pair of recesses and means for  
3 securing comprises a pair of prongs which are received in  
4 the recesses.

1 45. A device as in claim 44, wherein the shaft  
2 comprises said pair of prongs.

1 46. A device as in claim 45, wherein the means  
2 for selectively detaching the fastener comprises a rod  
3 and means for axially advancing the rod relative to the  
4 shaft to push the fastener off the securing means.

1 47. A suturing device comprising:  
2 an elongate guide body having a proximal end  
3 and a distal end;

4 a guide tip at the distal end of the guide  
5 body, said guide tip having a pair of needle guide  
6 channels;

7 a pair of needles which are slidably disposed  
8 in the needle guide channels; each of said needles having  
9 a sharpened distal tip;

10 a length of suture extending between and  
11 secured to said needles; and

12 means for reciprocating said needles between a  
13 distally retracted position where the needle tips are  
14 spaced distally from the distal end of the guide body and

15 a proximally extended position where the needle tips  
16 extend past the proximal end of the guide body.

1 48. A suturing device as in claim 47, wherein  
2 a recessed tissue-receiving region is formed between the  
3 proximal ends of needle guide channels and the distal end  
4 of the guide body, whereby a tissue puncture conforming  
5 to the tissue-receiving region will be configured to  
6 receive the needles on opposite sides of the puncture.

1 49. A suturing device as in claim 48, further  
2 comprising means on the guide body for receiving the  
3 needles from the tissue-receiving gap and passing said  
4 needles to the proximal end of the guide body as said  
5 needles are reciprocated proximally.

1 50. A suturing device as in claim 47, wherein  
2 the elongate guide body has a blood marker lumen having a  
3 distal port disposed so that it enters the blood vessel  
4 when the guide tip is properly positioned therein and a  
5 proximal port which displays blood when the distal port  
6 has entered the blood vessel.

1 51. A suturing device as in claim 47, wherein  
2 the needles are longer than the guide body.

1 52. A suturing device as in claim 47, further  
2 comprising a flexible sheath attached to the distal end  
3 of the guide tip, wherein the needles are held within the  
4 sheath when they are in their distally retracted  
5 position.

1 53. A suturing device as in claim 47, wherein  
2 the needle reciprocating means comprises a flexible shaft  
3 having a proximal end and a distal end which is  
4 reciprocatably received in the guide body and which  
5 carries the needles near its distal end.

1                   54. A suturing device as in claim 53, wherein  
2                   the needles are removably carried on the shaft.

1                   55. A suturing device as in claim 53, wherein  
2                   the needles are fixedly carried on the shaft and wherein  
3                   the suture is attached near the sharpened tip of each  
4                   needle.

1                   56. A method for sealing a puncture site in a  
2                   blood vessel wall disposed at the distal end of a  
3                   percutaneous tissue tract, said method comprising:  
4                   forming a suture loop which passes through  
5                   penetrations in the blood vessel wall disposed on  
6                   opposite sides of the puncture site with free ends of the  
7                   suture passing out through the tissue tract; and  
8                   securing the free ends of the suture to close  
9                   the puncture site.

1                   57. A method as in claim 56, wherein the  
2                   suture loop forming step comprises positioning a shaft  
3                   through the tissue tract so that a pair of needles having  
4                   a length of suture therebetween engage needle penetration  
5                   sites on opposite sides of the puncture site, drawing the  
6                   shaft outwardly to guide the needles through the  
7                   penetration site into the tissue tract, and removing the  
8                   free ends of the suture from the needles.

1                   58. A method as in claim 56, further  
2                   comprising maintaining an introducer sheath in the tissue  
3                   tract, wherein the needle-holding shaft is positioned  
4                   through said introducer sheath.

1                   59. A method as in claim 56, wherein the  
2                   suture securing step comprises tying the free ends into a  
3                   knot and positioning the knot against the adventitial  
4                   wall of the blood vessel.

1                   60. A method as in claim 56, wherein the  
2                   suture securing step comprises introducing a fastener  
3                   over the free ends of the suture.

1                   61. An improved method for sealing a puncture  
2                   site in a blood vessel wall disposed at the distal end of  
3                   a percutaneous tissue tract, wherein the improvement  
4                   comprises suturing the blood vessel wall through the  
5                   percutaneous tissue tract and securing the suture near  
6                   the distal end of the tissue tract over the adventitial  
7                   wall of the blood vessel.



FIG. 1

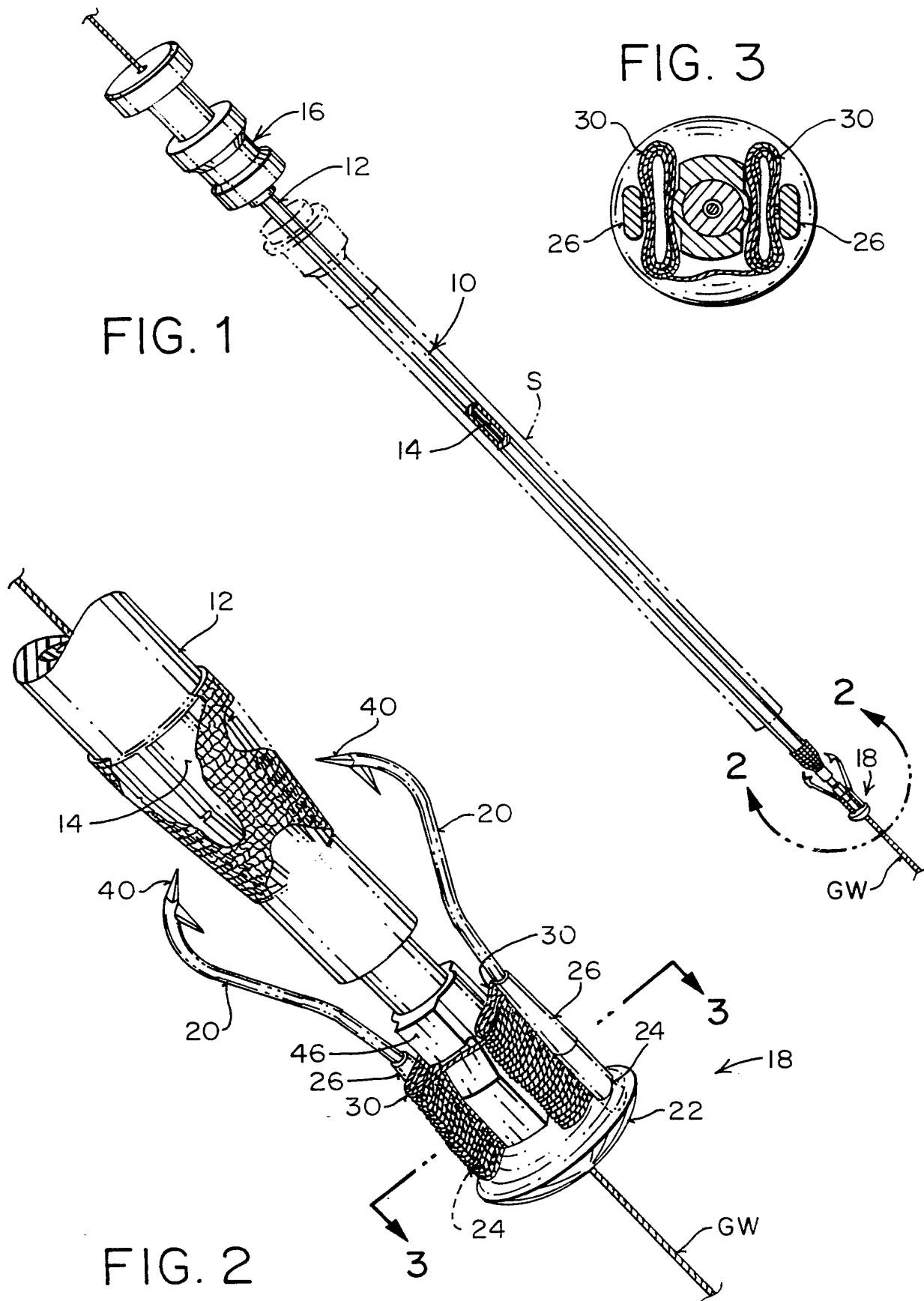


FIG. 3

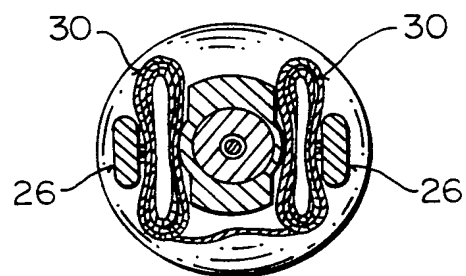


FIG. 2

FIG. 4

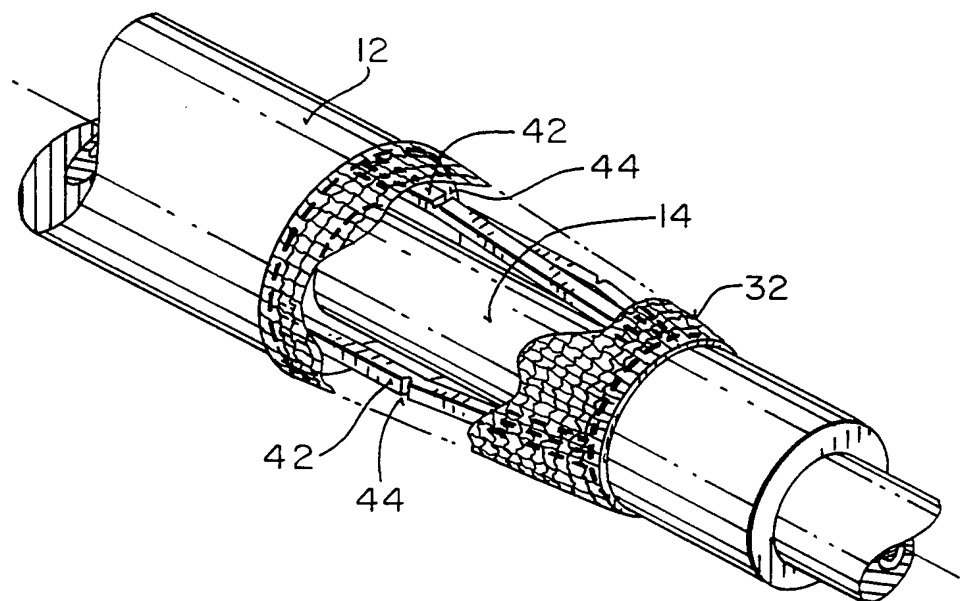


FIG. 5

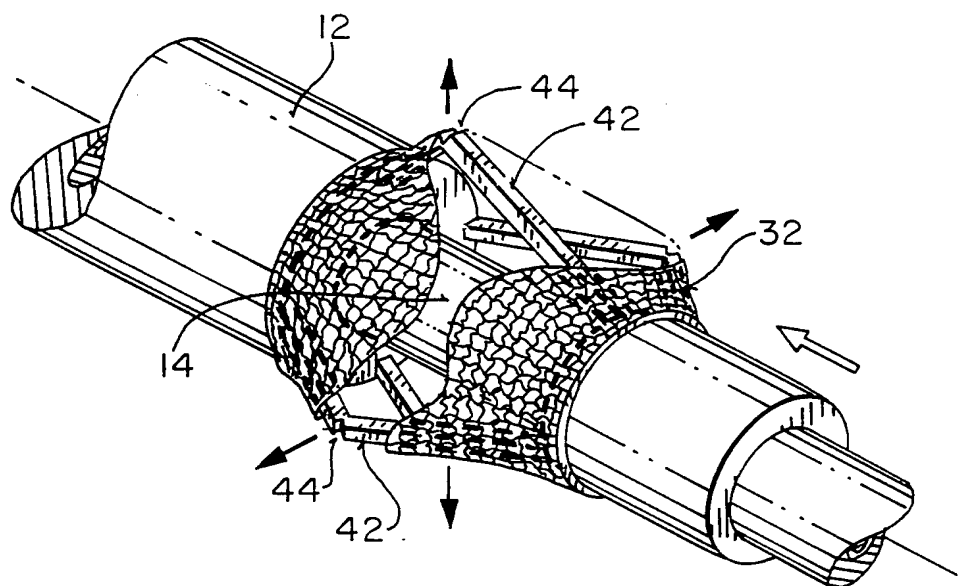


FIG. 6

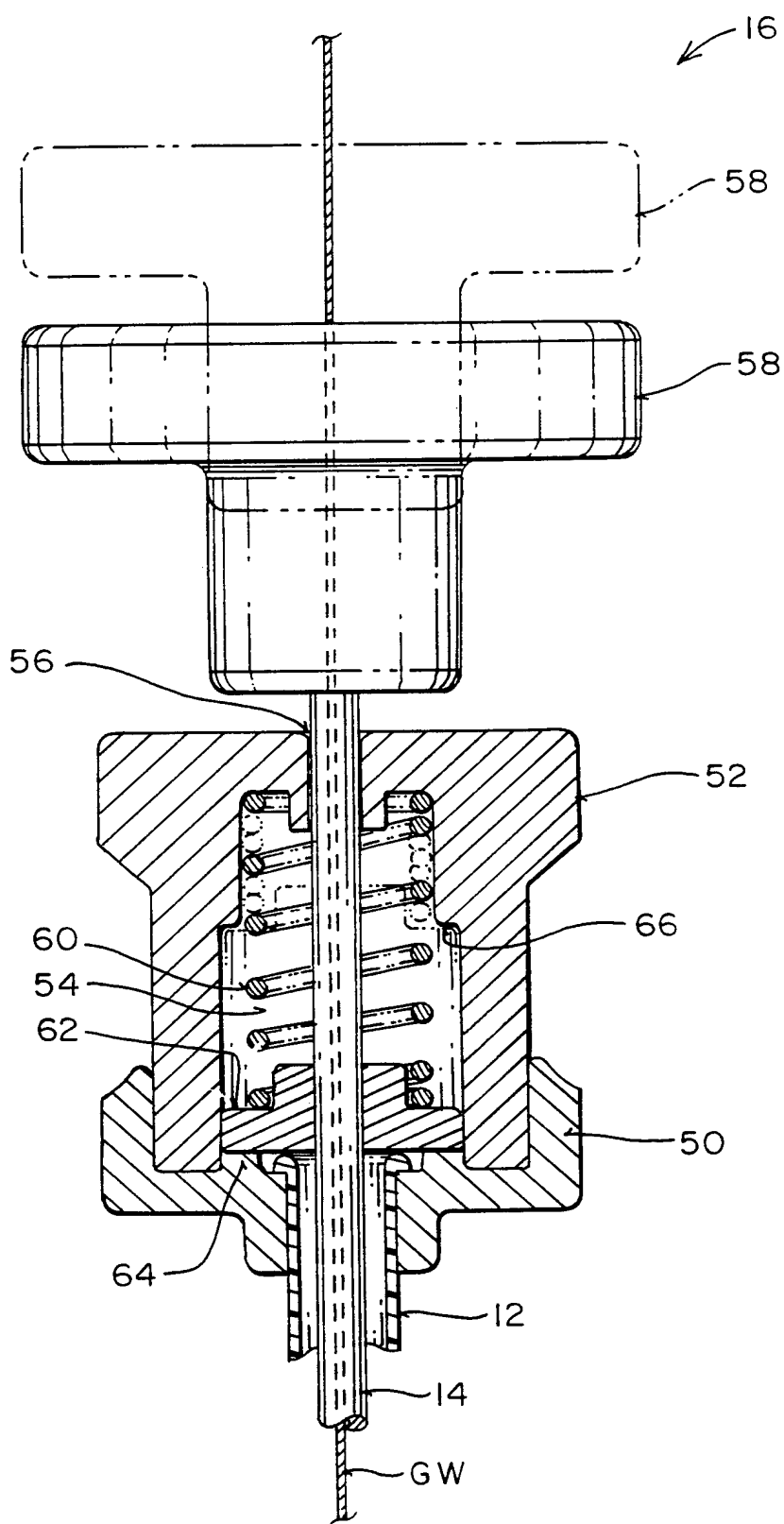


FIG. 7

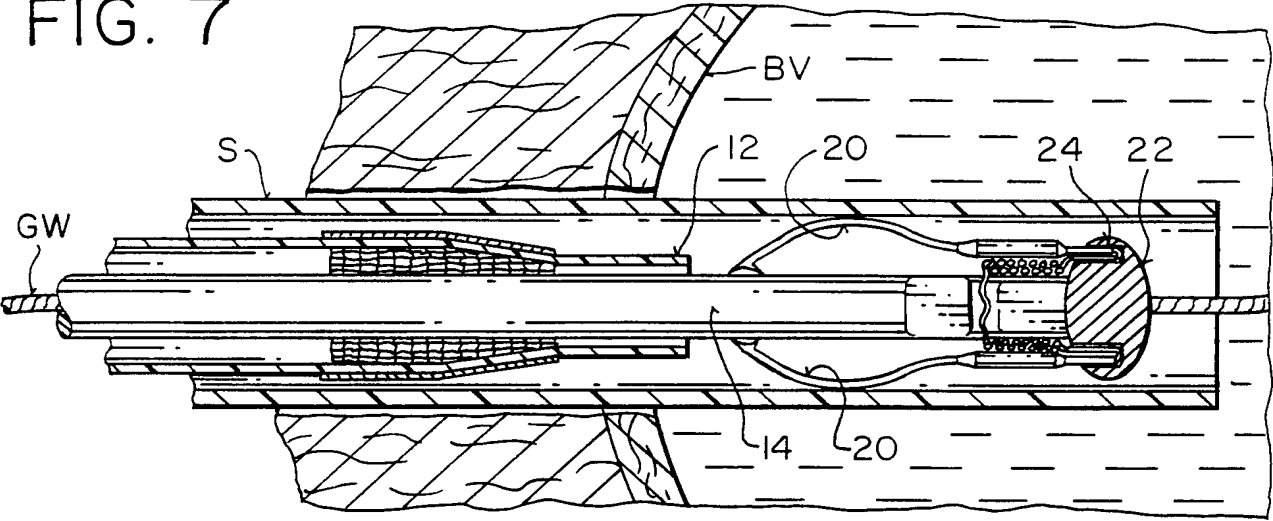


FIG. 8

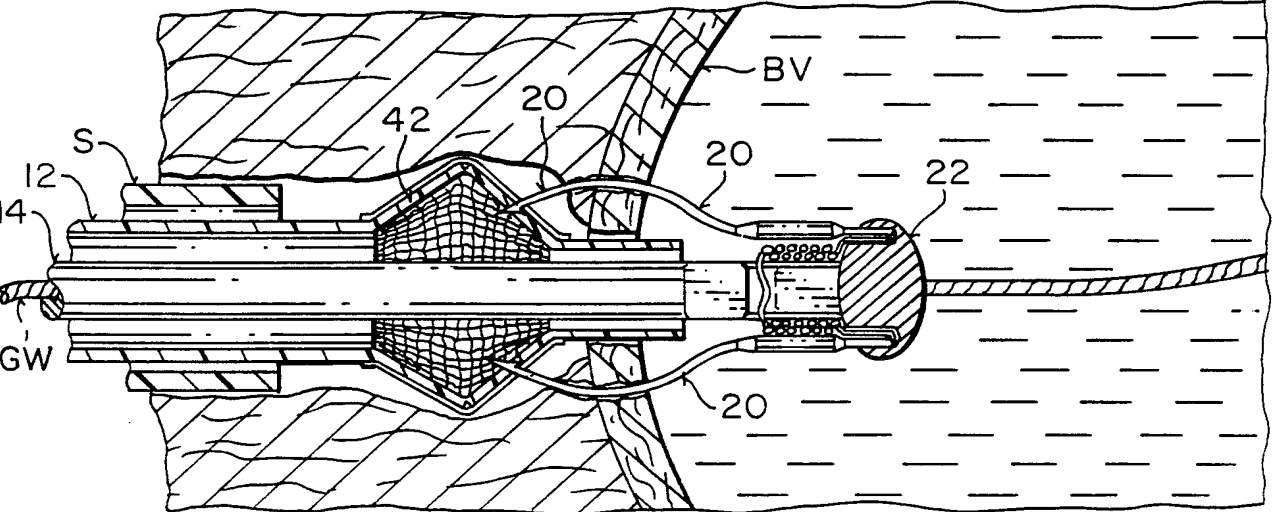
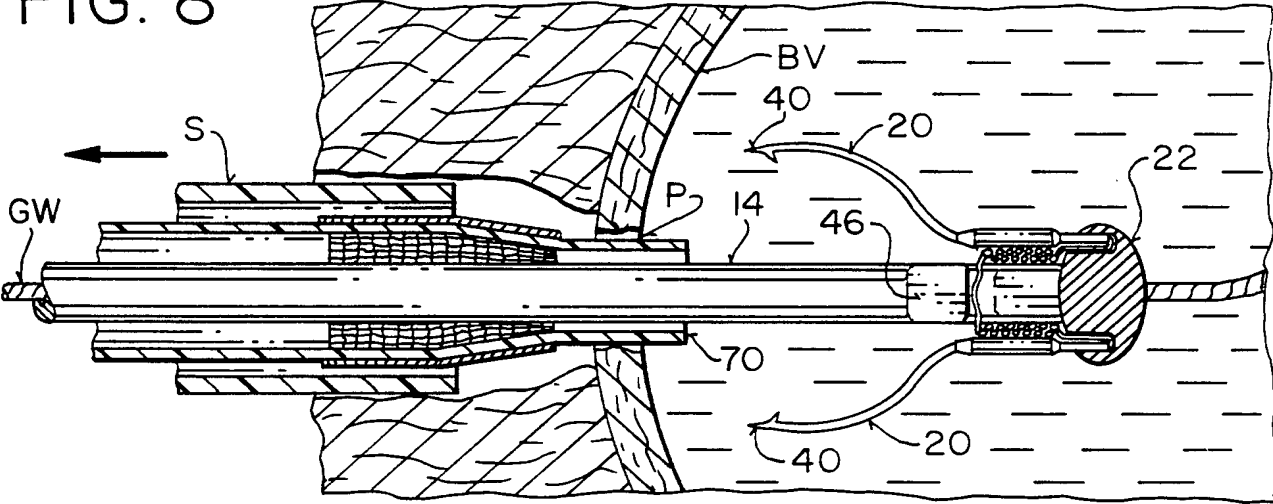


FIG. 9

FIG. 10

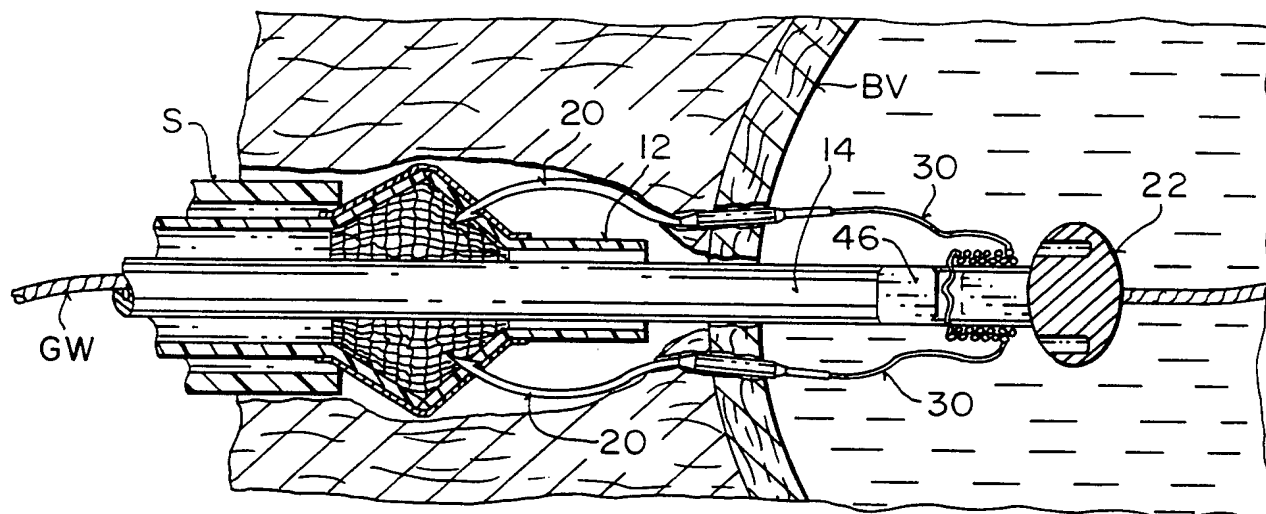


FIG. 11

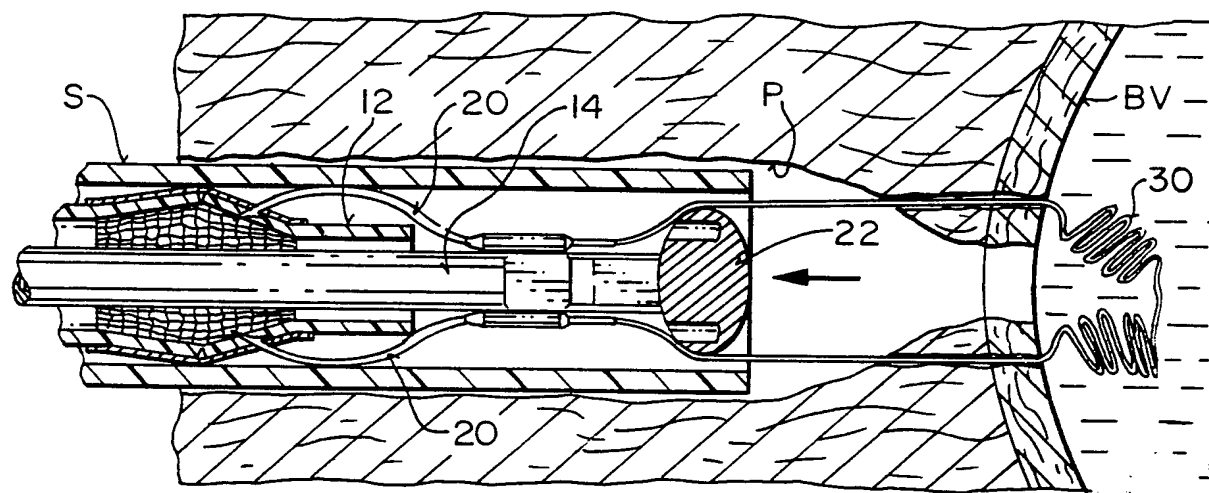


FIG. 12

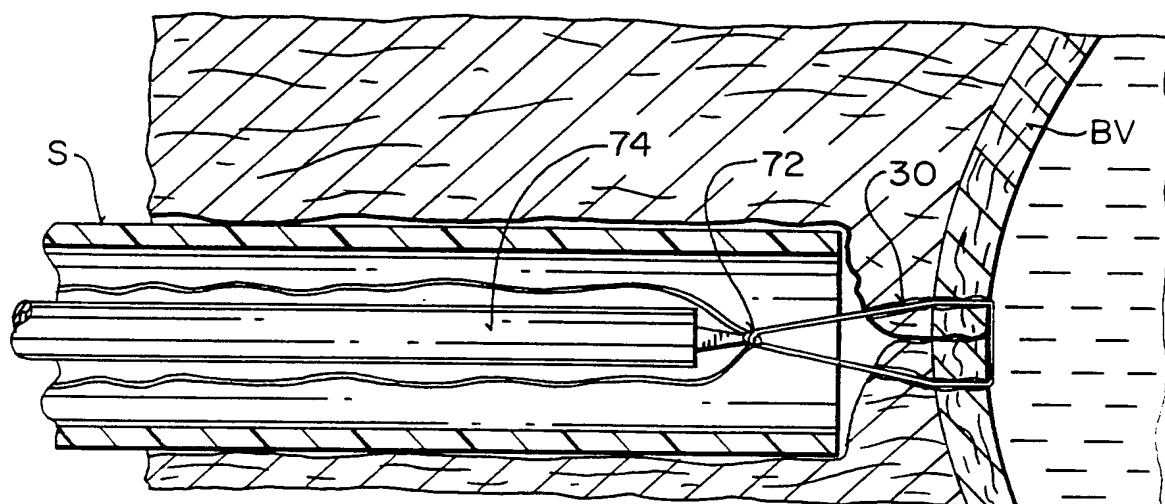


FIG. 13

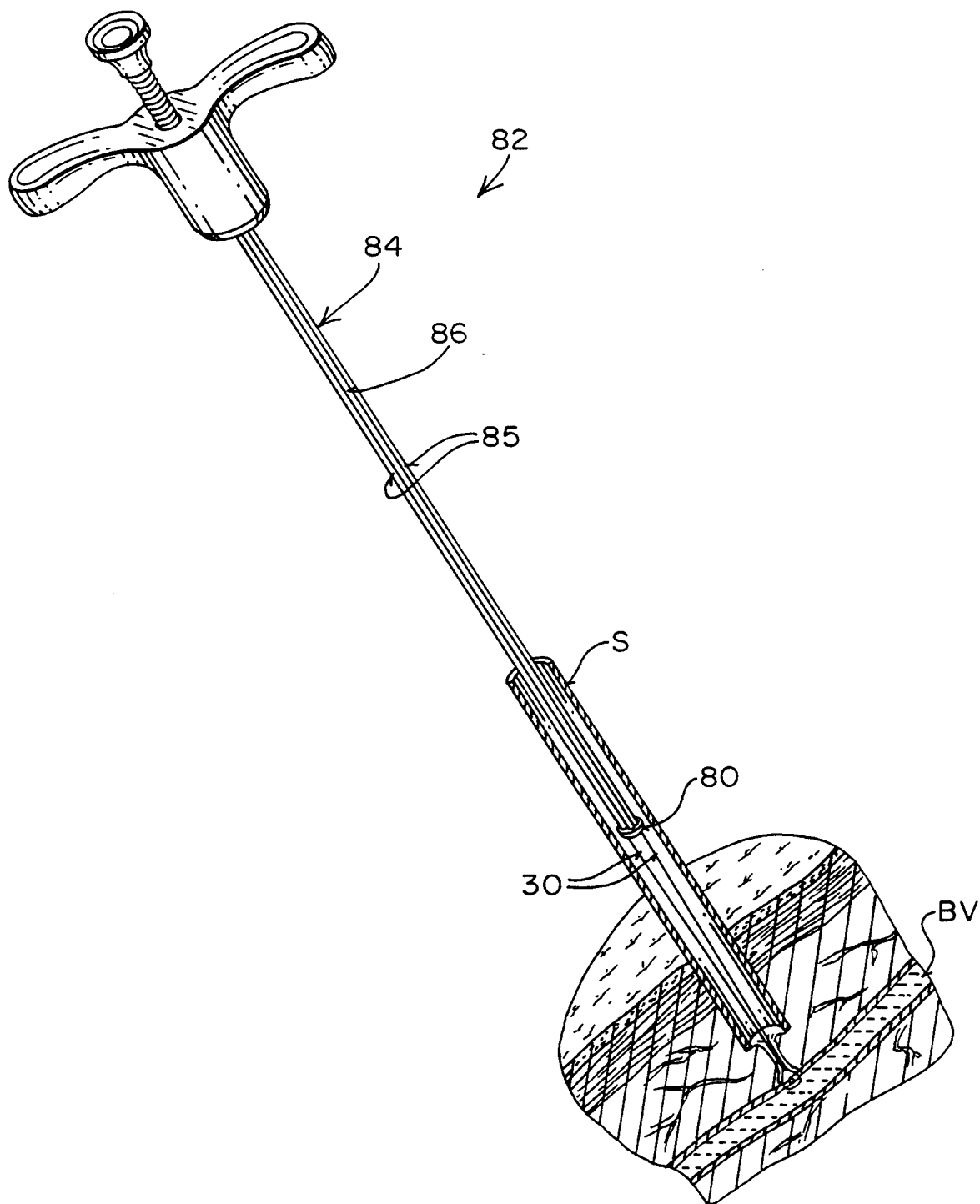


FIG. 14

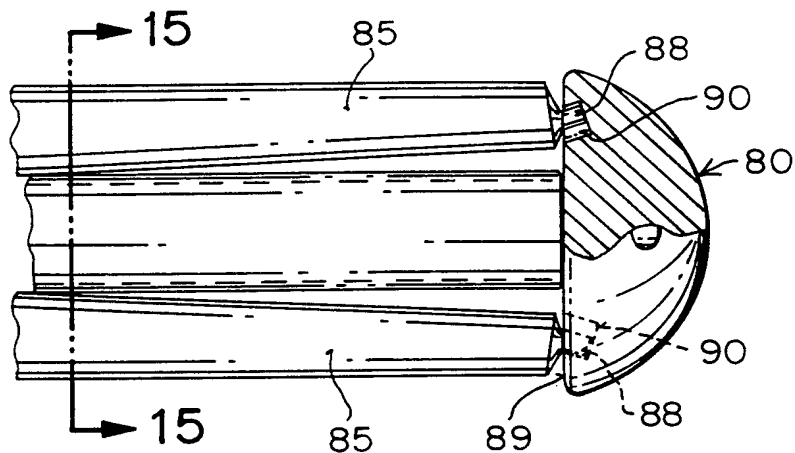


FIG. 15

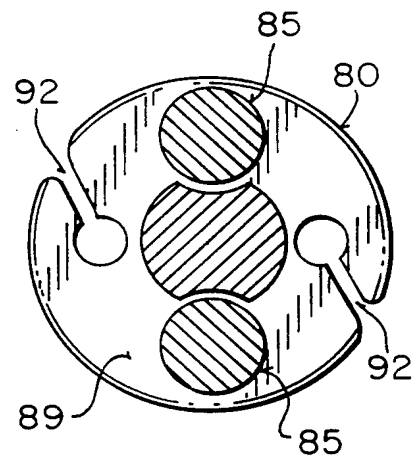


FIG. 18

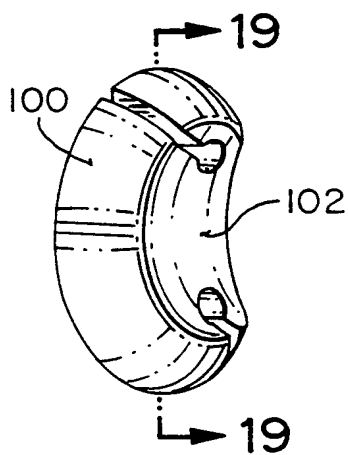


FIG. 20

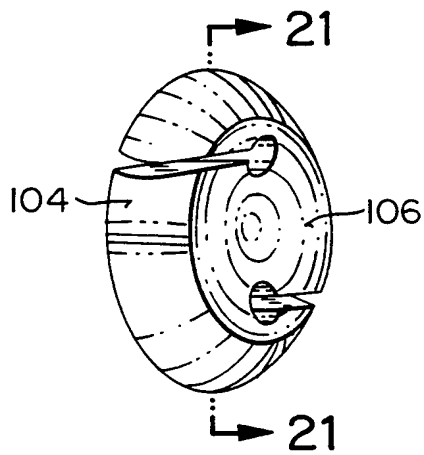


FIG. 22

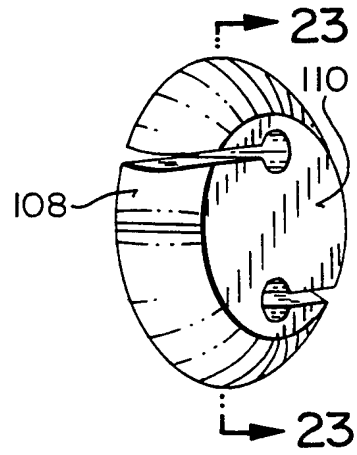


FIG. 19

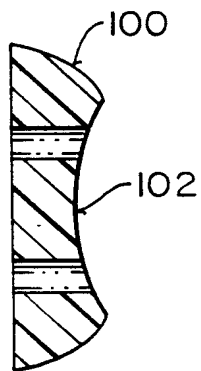


FIG. 21

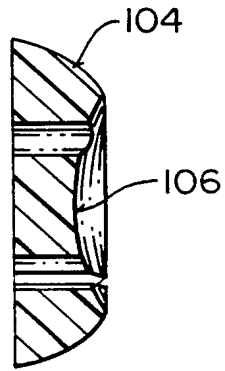


FIG. 23

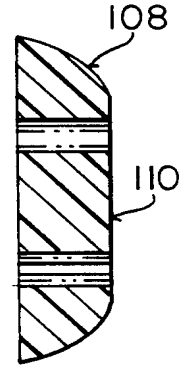


FIG. 16

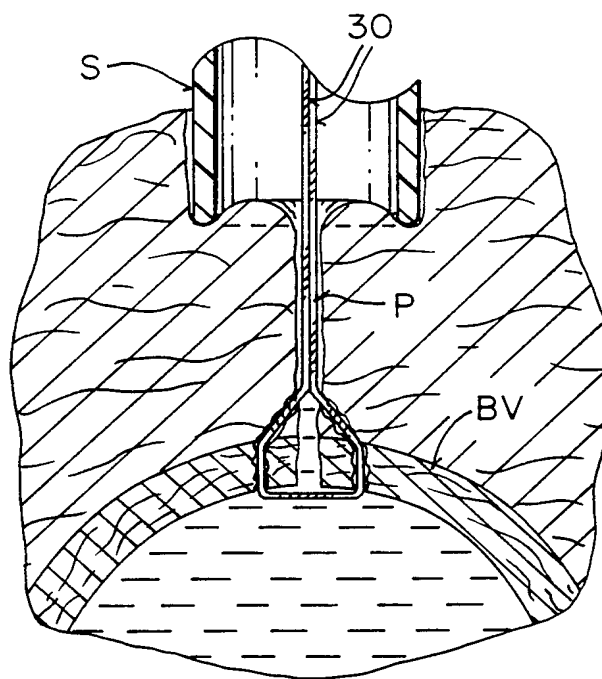
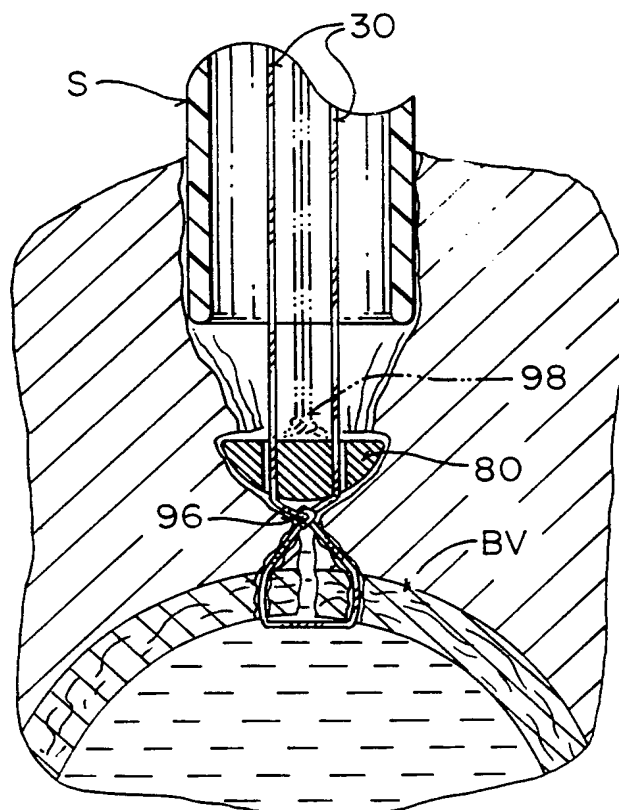


FIG. 17





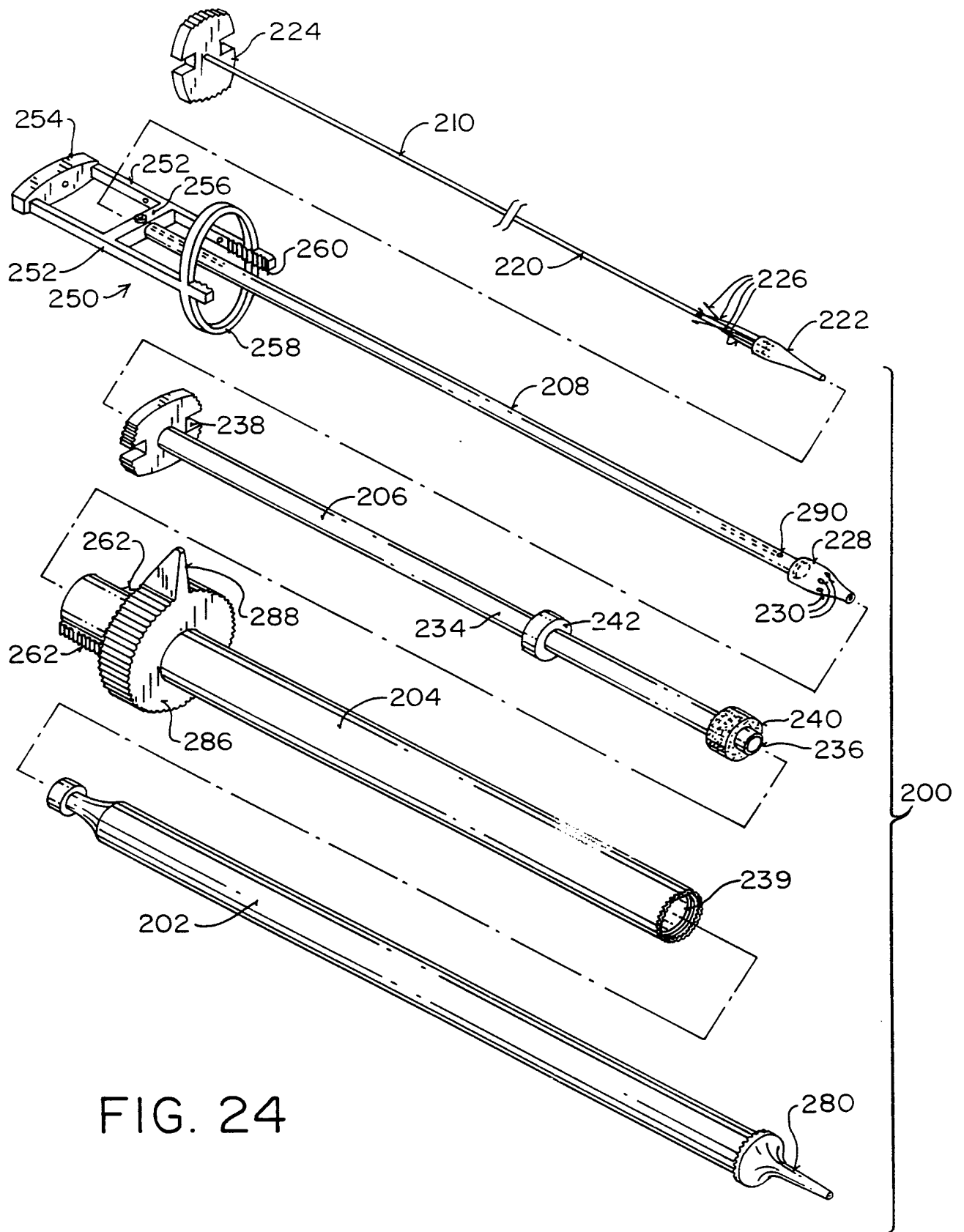


FIG. 24

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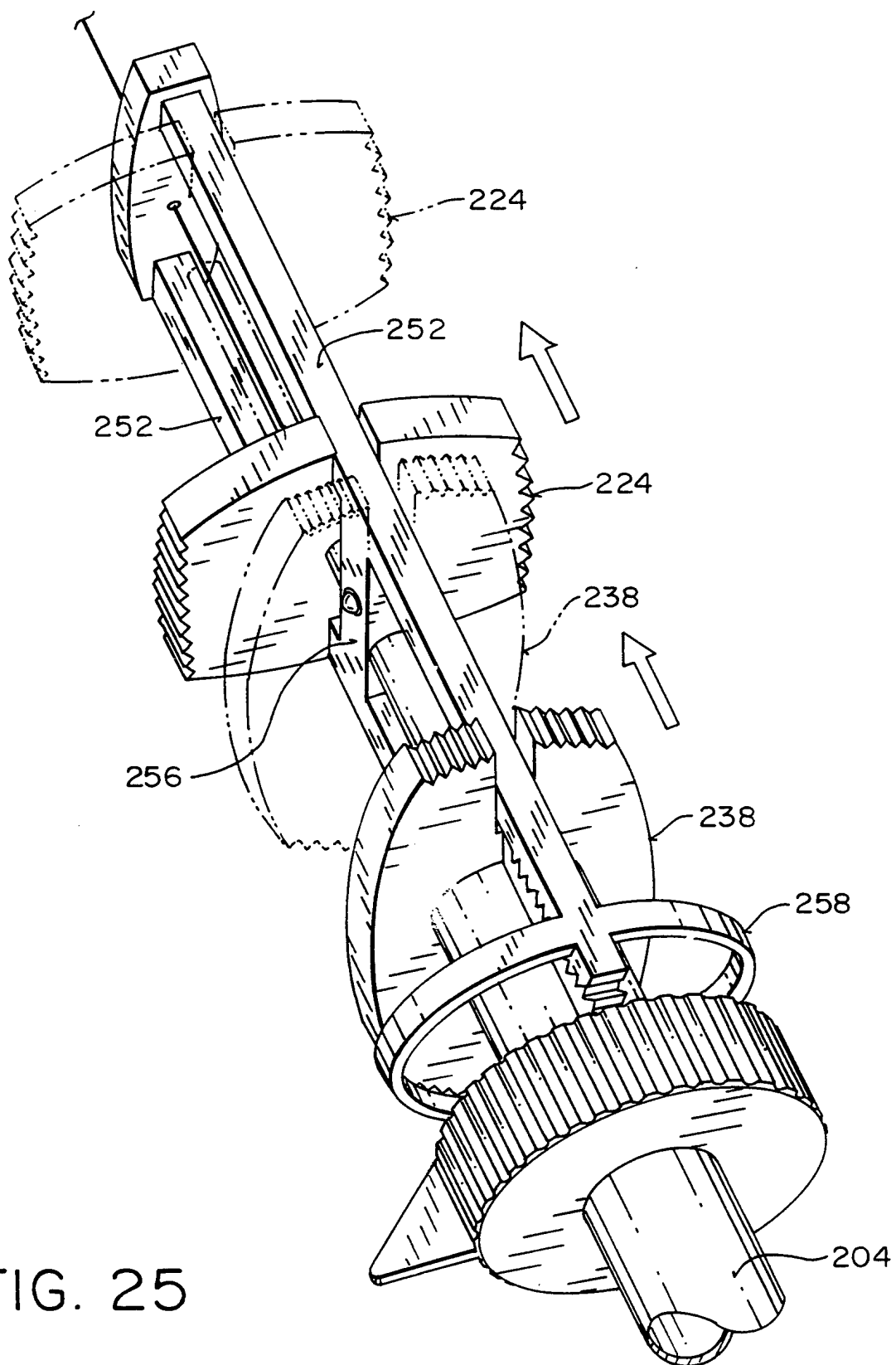


FIG. 25

11/21

FIG. 26A

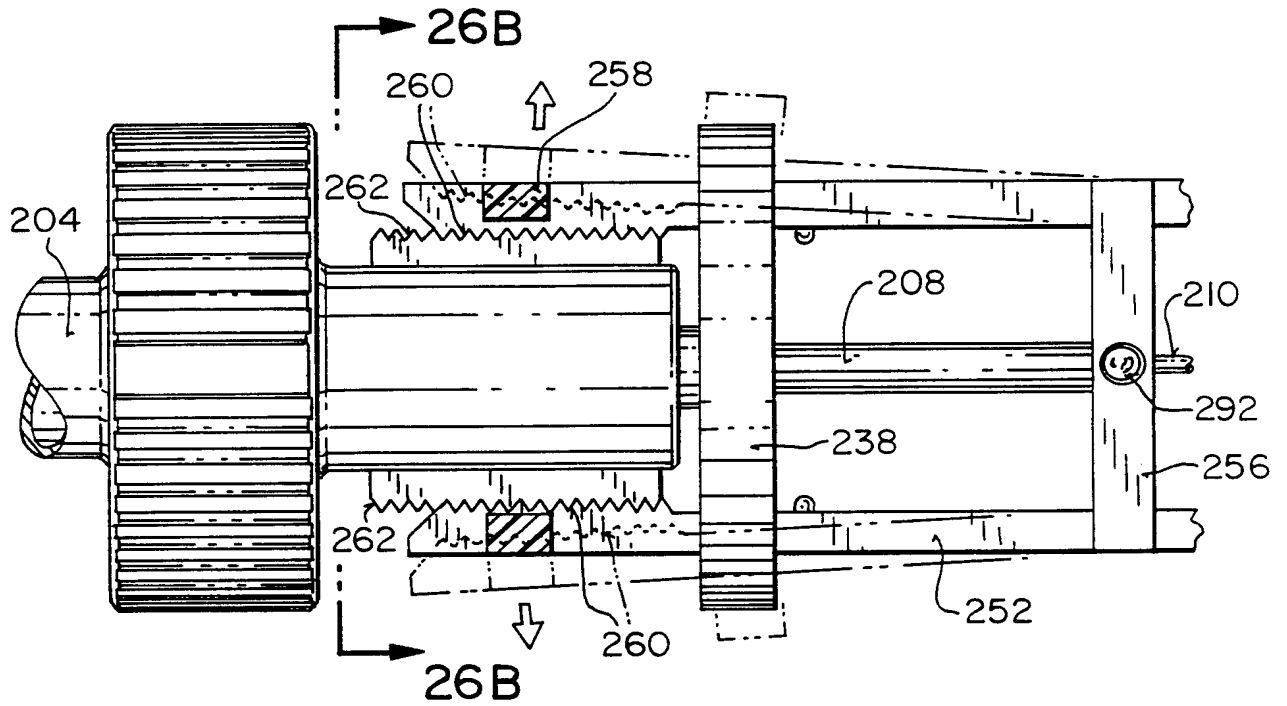
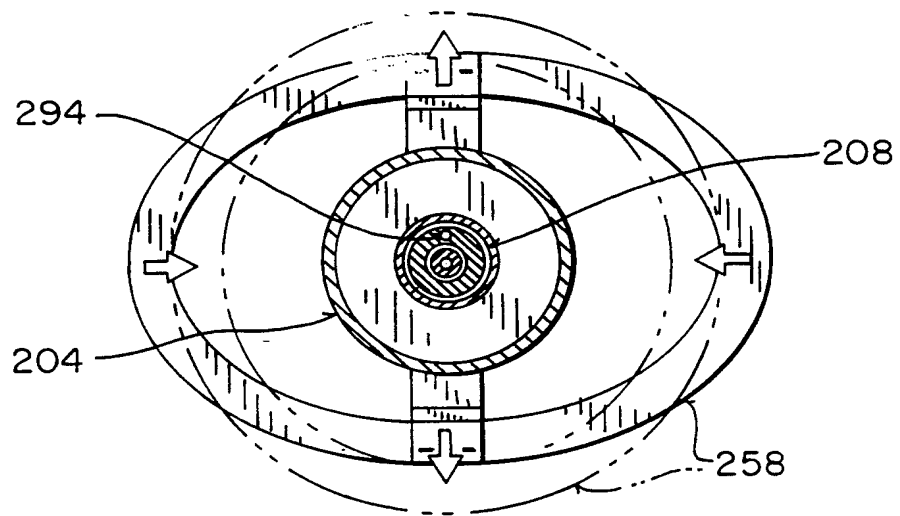


FIG. 26B



12/21

FIG. 27A

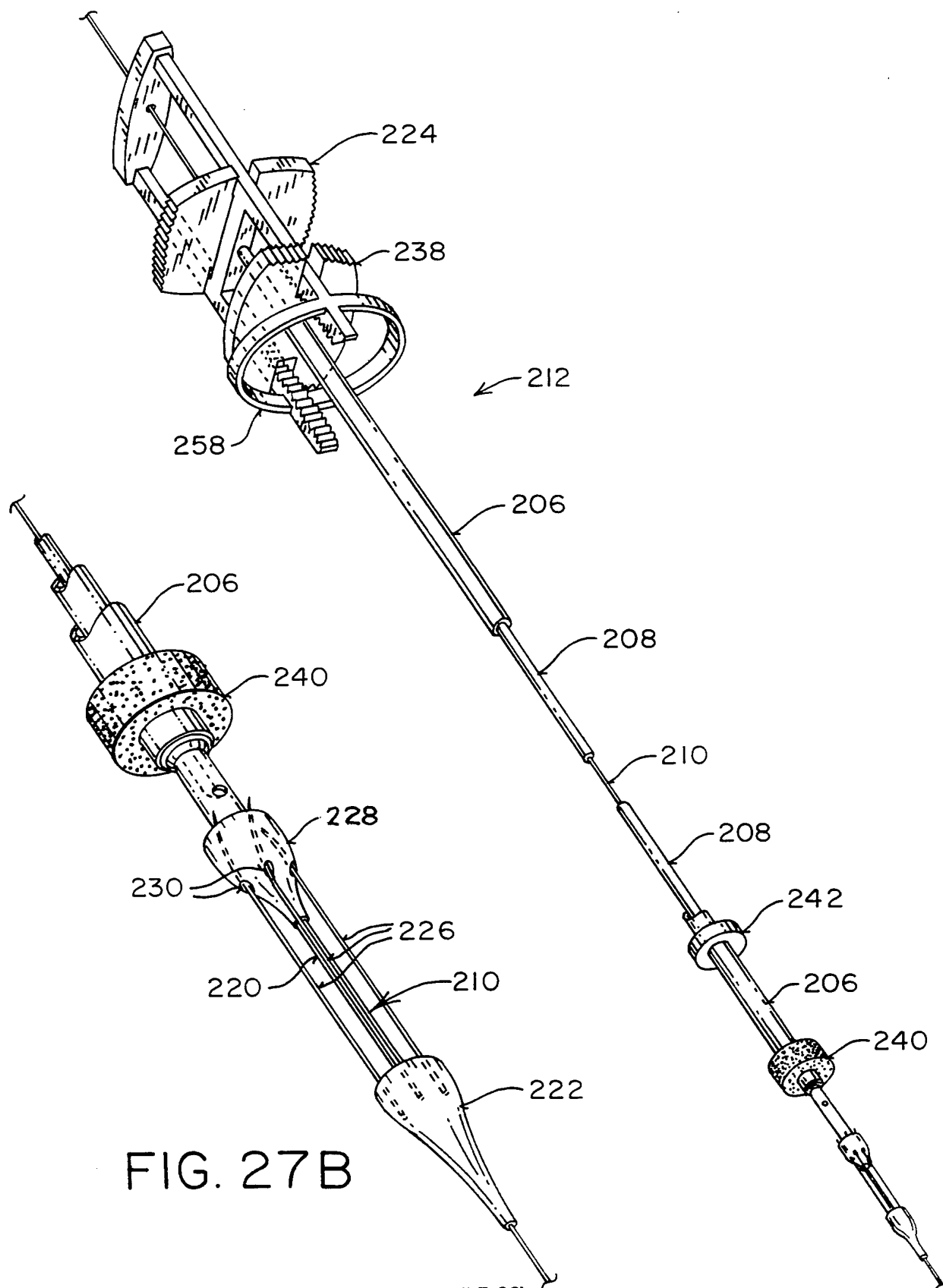


FIG. 27B

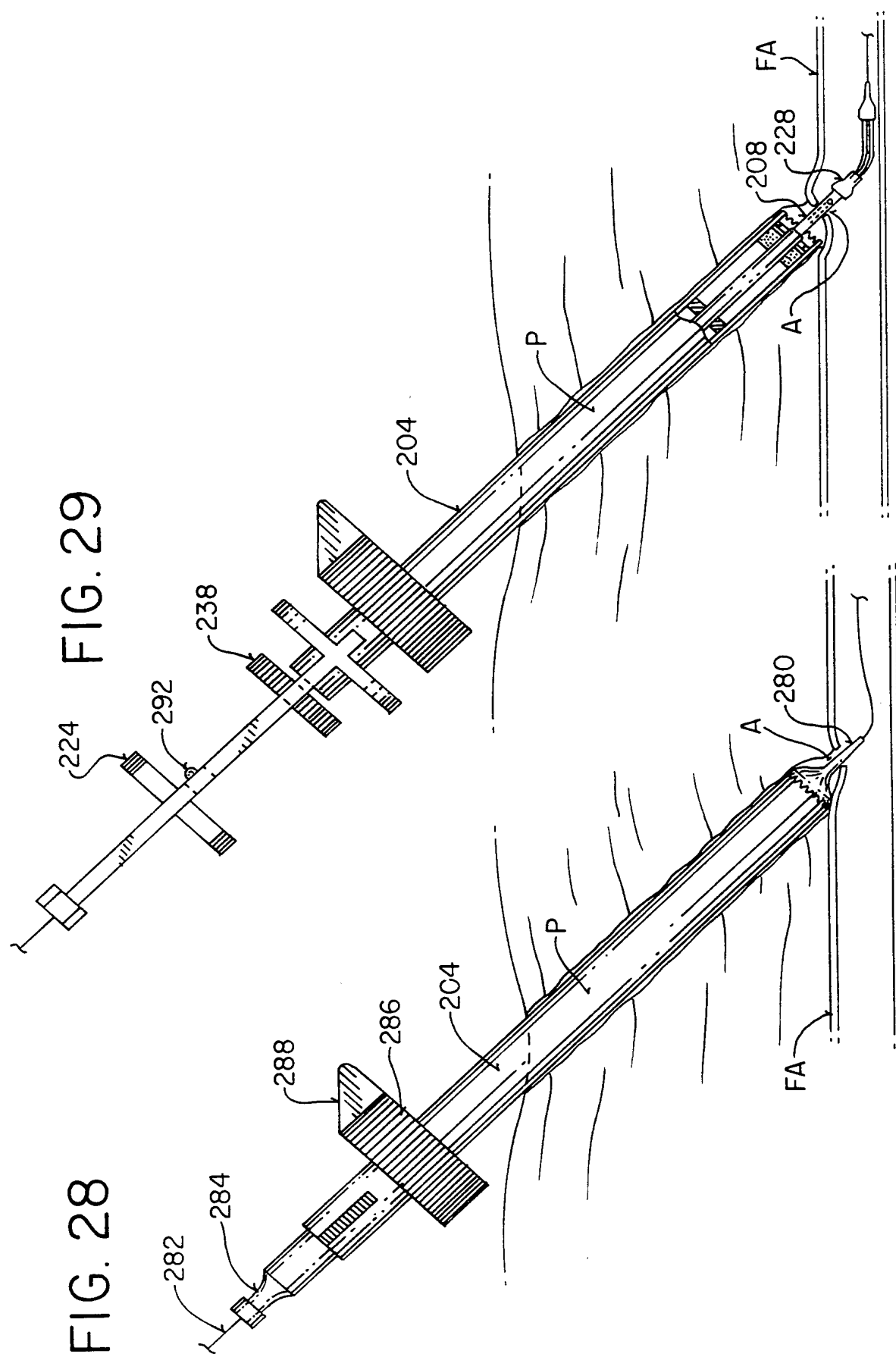


FIG. 30B

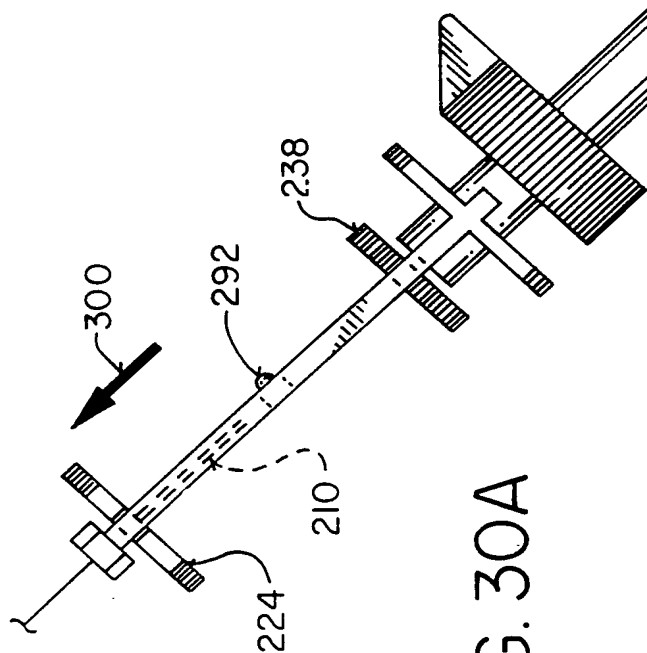
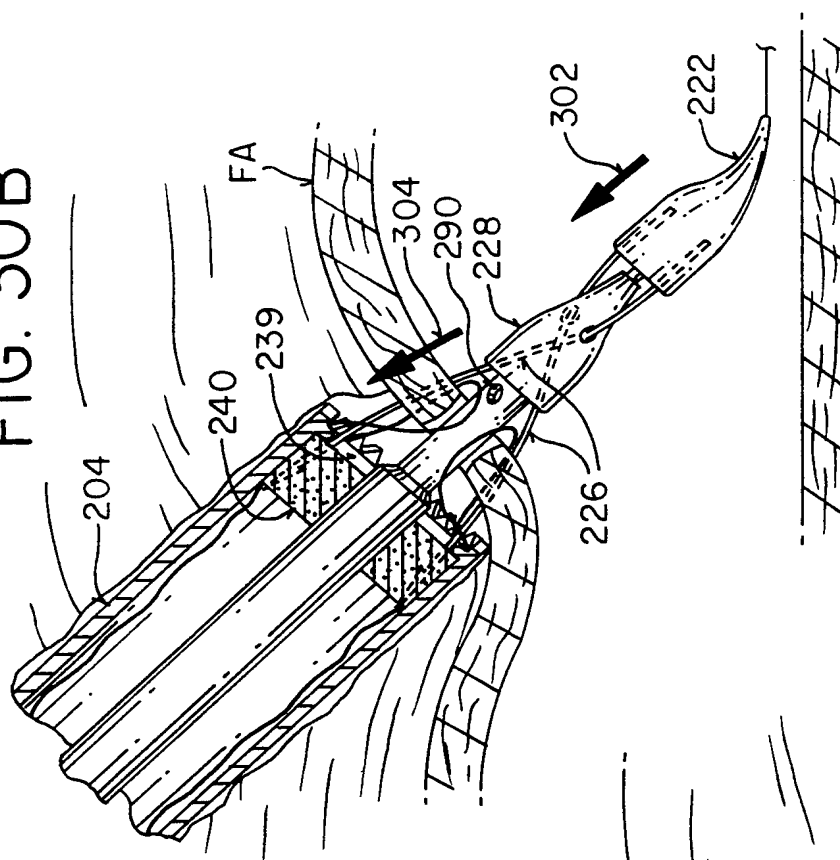


FIG. 30A

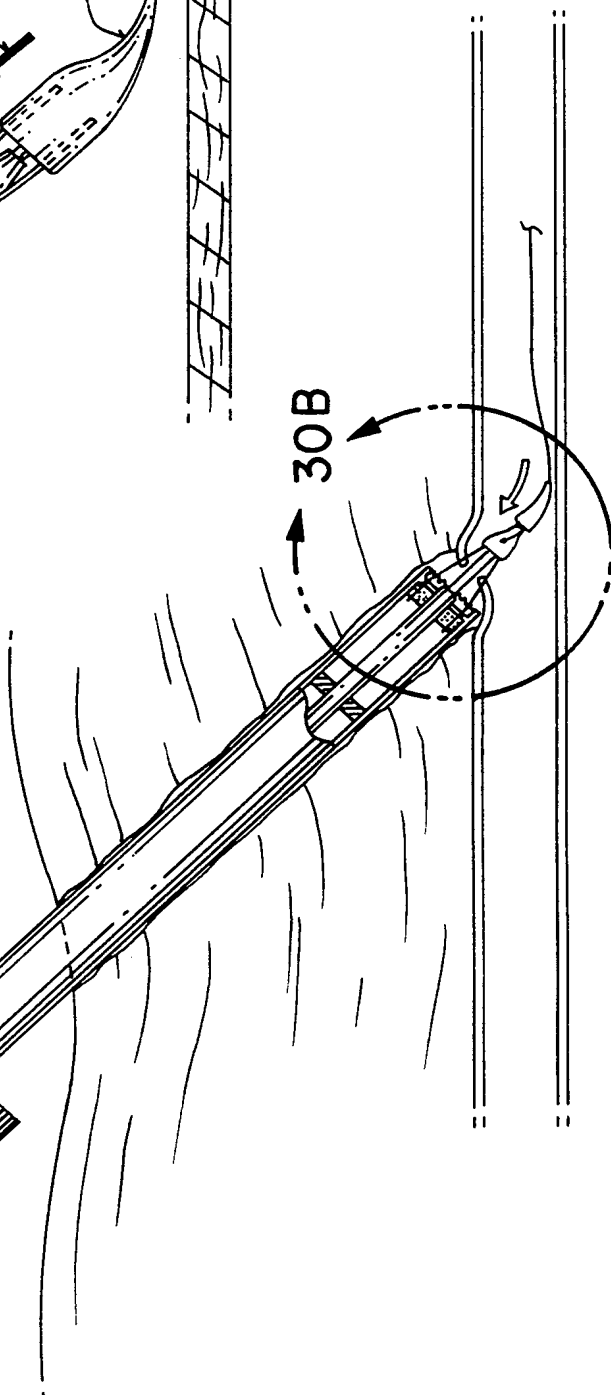


FIG. 31B

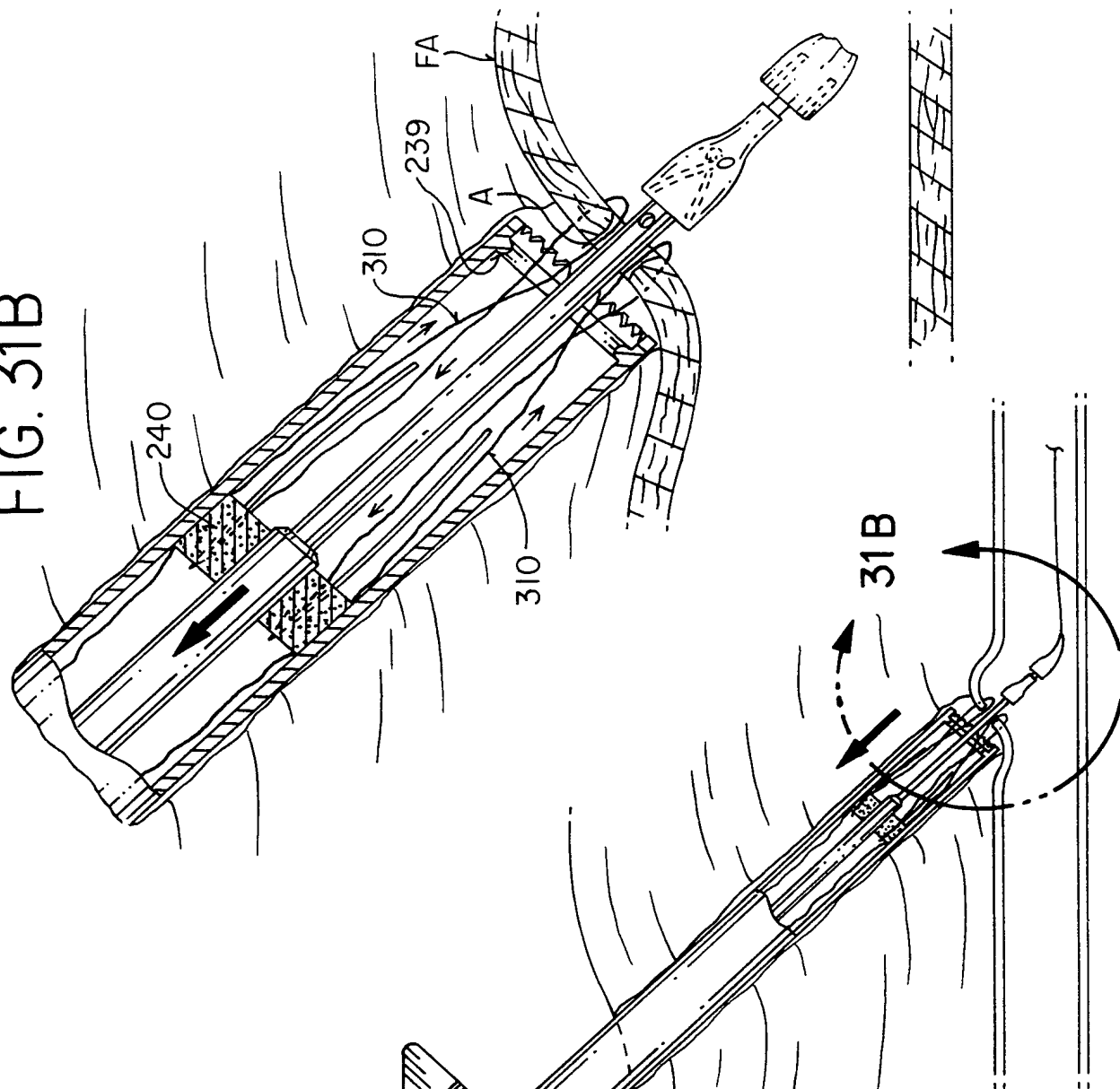


FIG. 31A

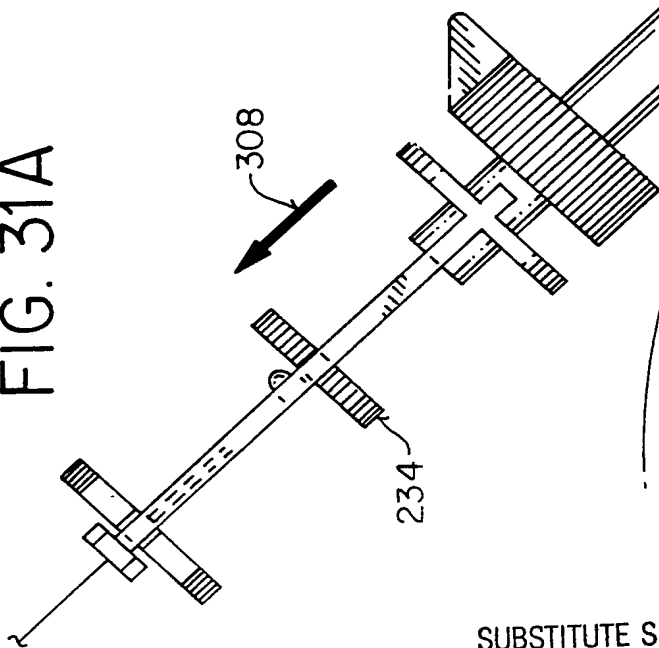


FIG. 32

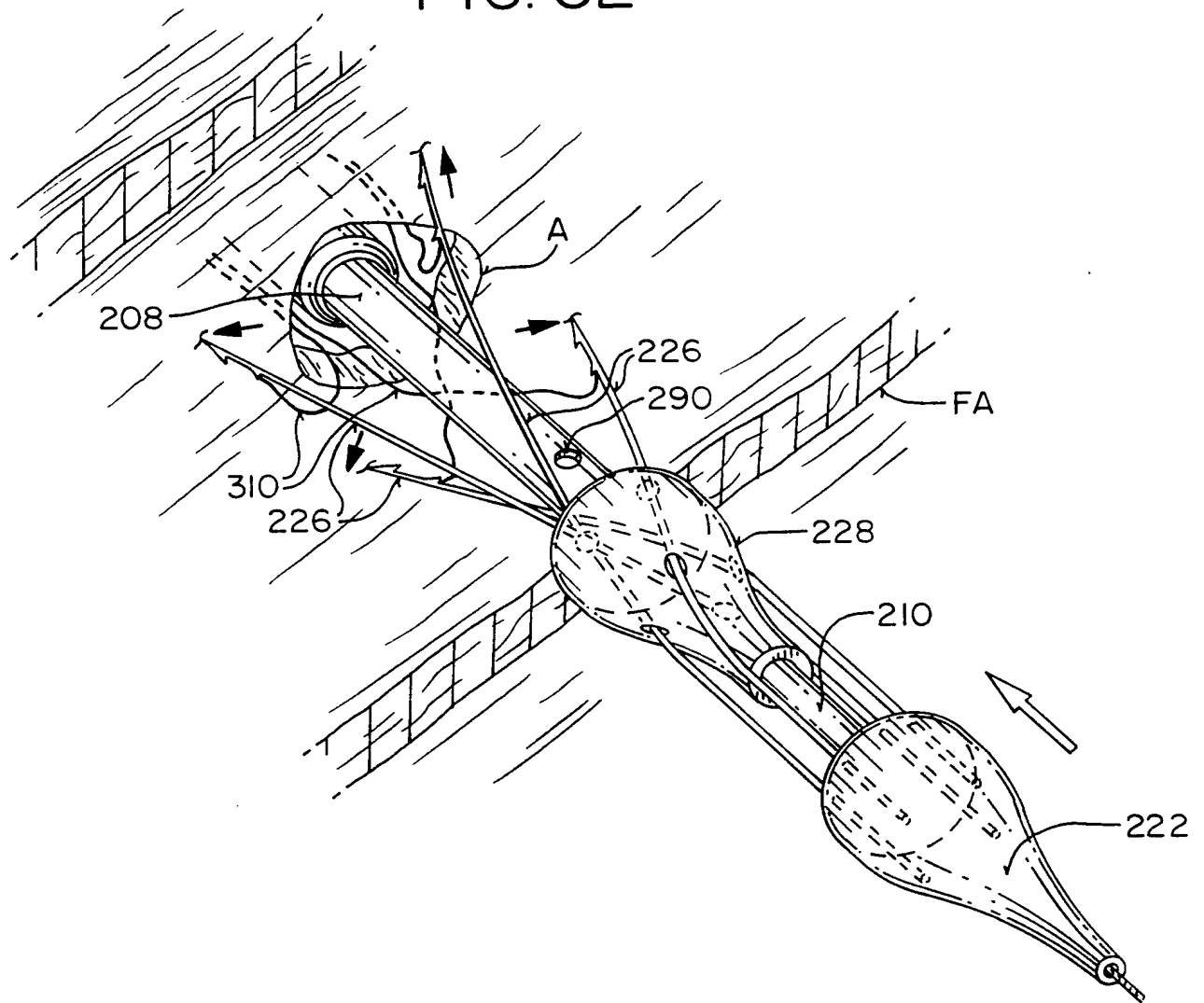


FIG. 33

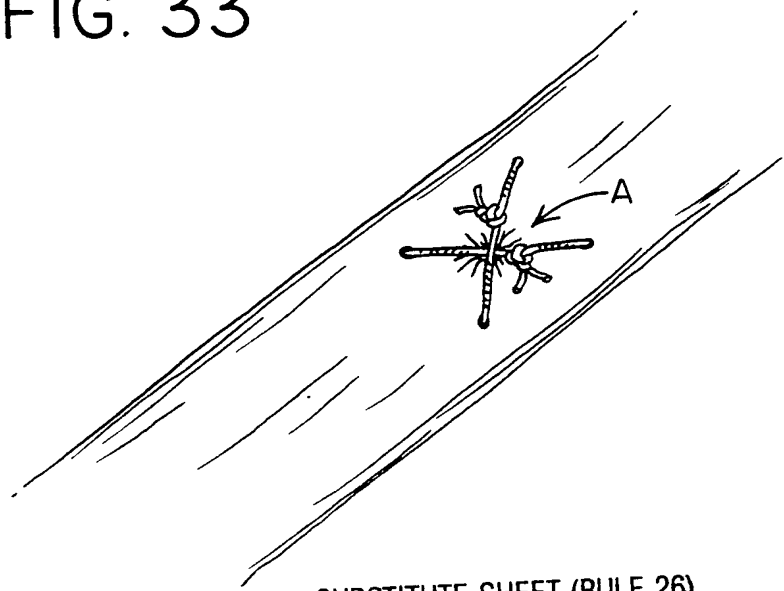




FIG. 34

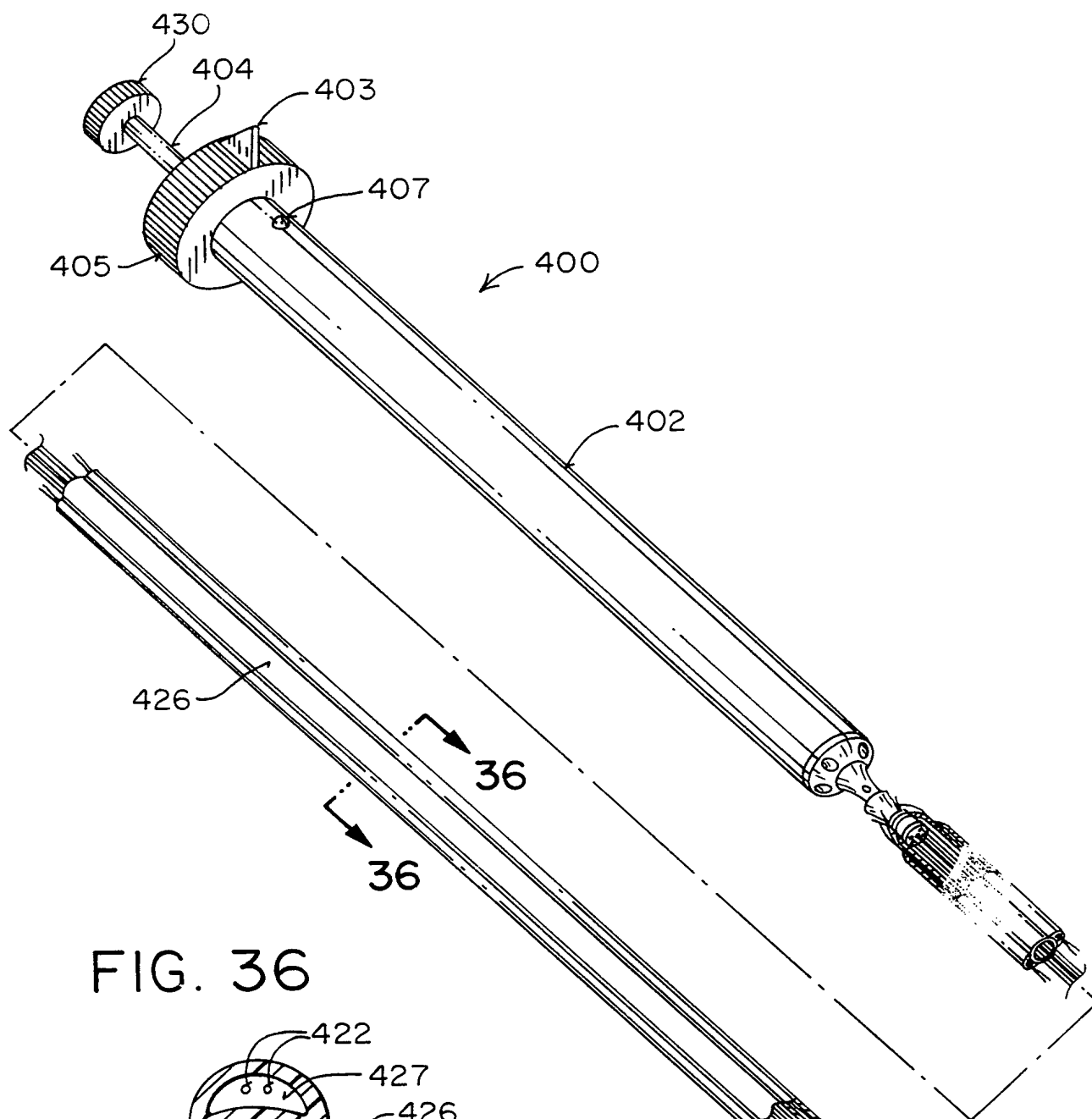


FIG. 36

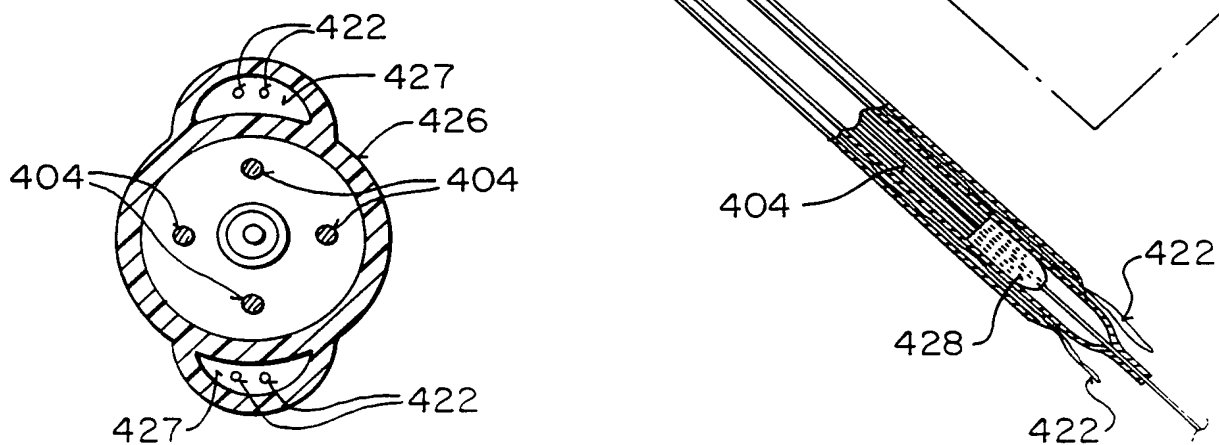


FIG. 35A

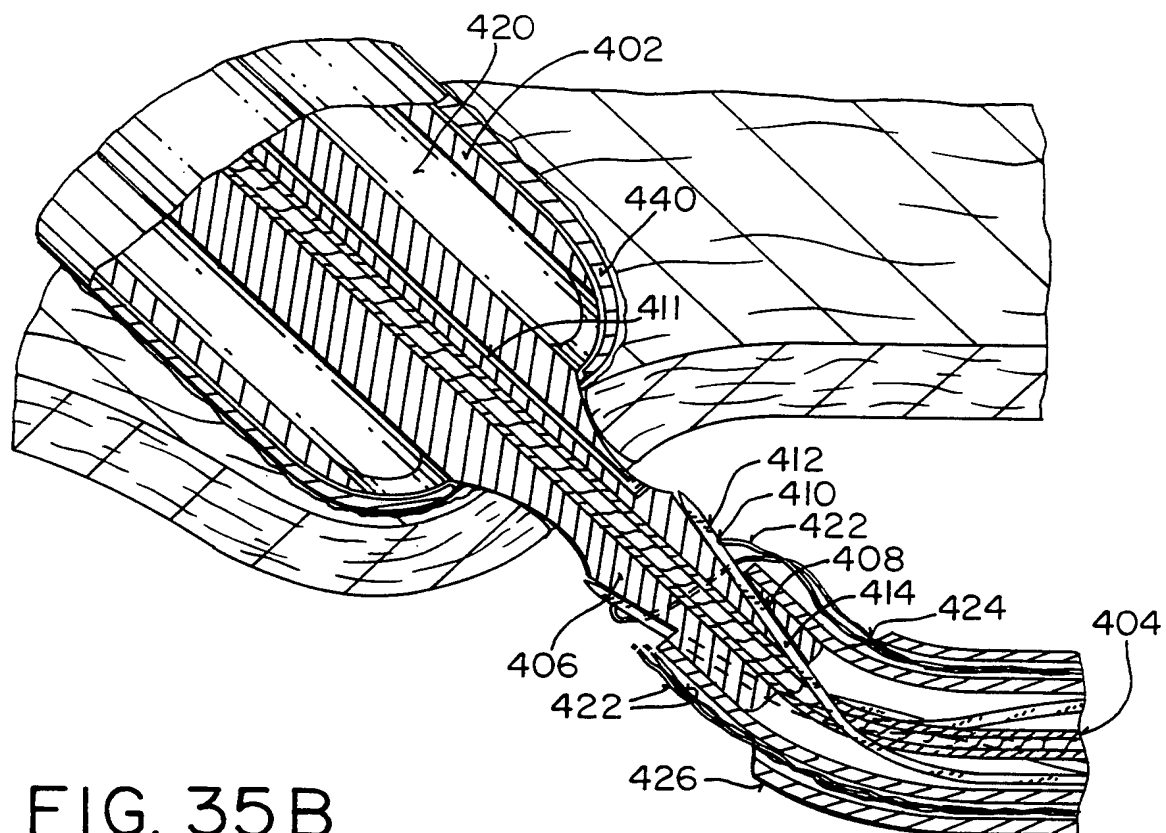
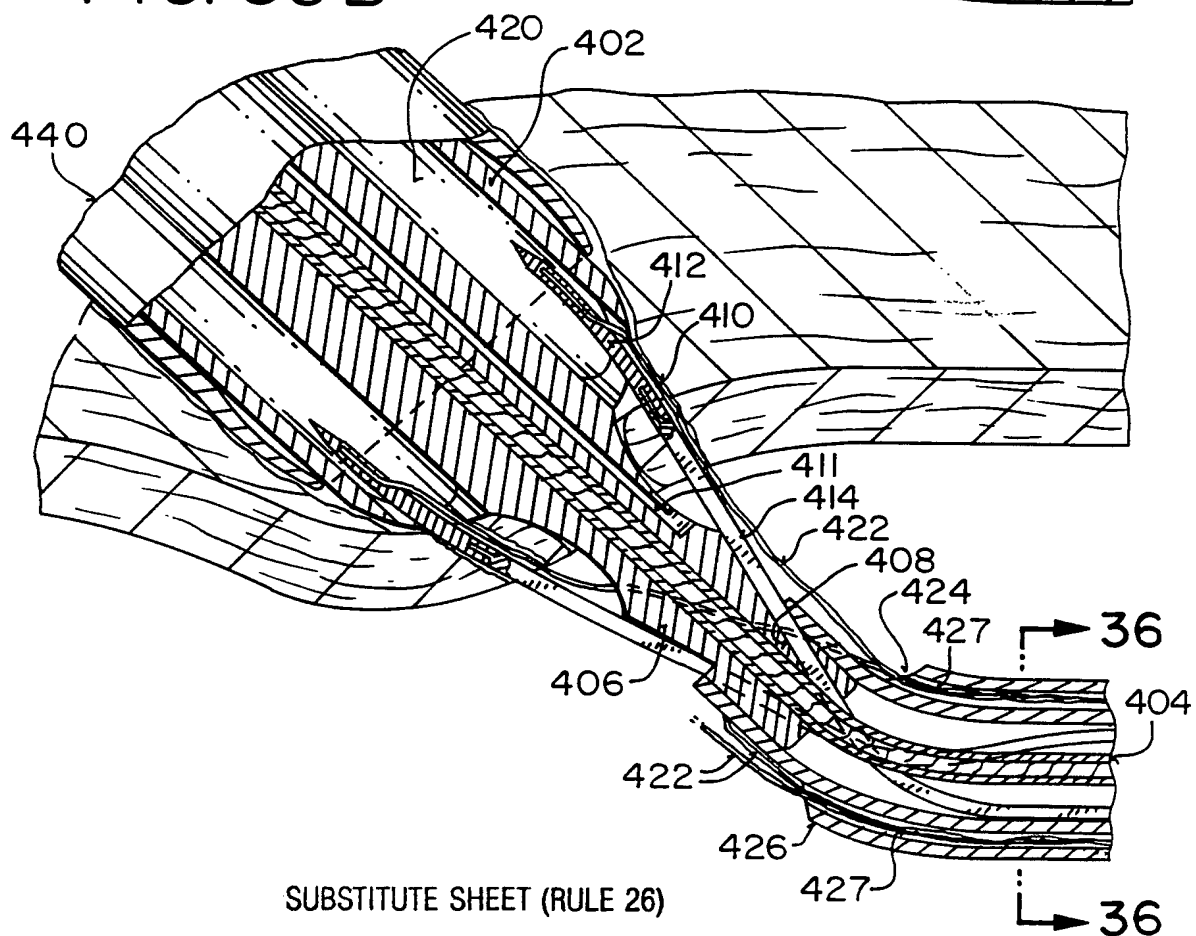


FIG. 35B



SUBSTITUTE SHEET (RULE 26)

FIG. 37

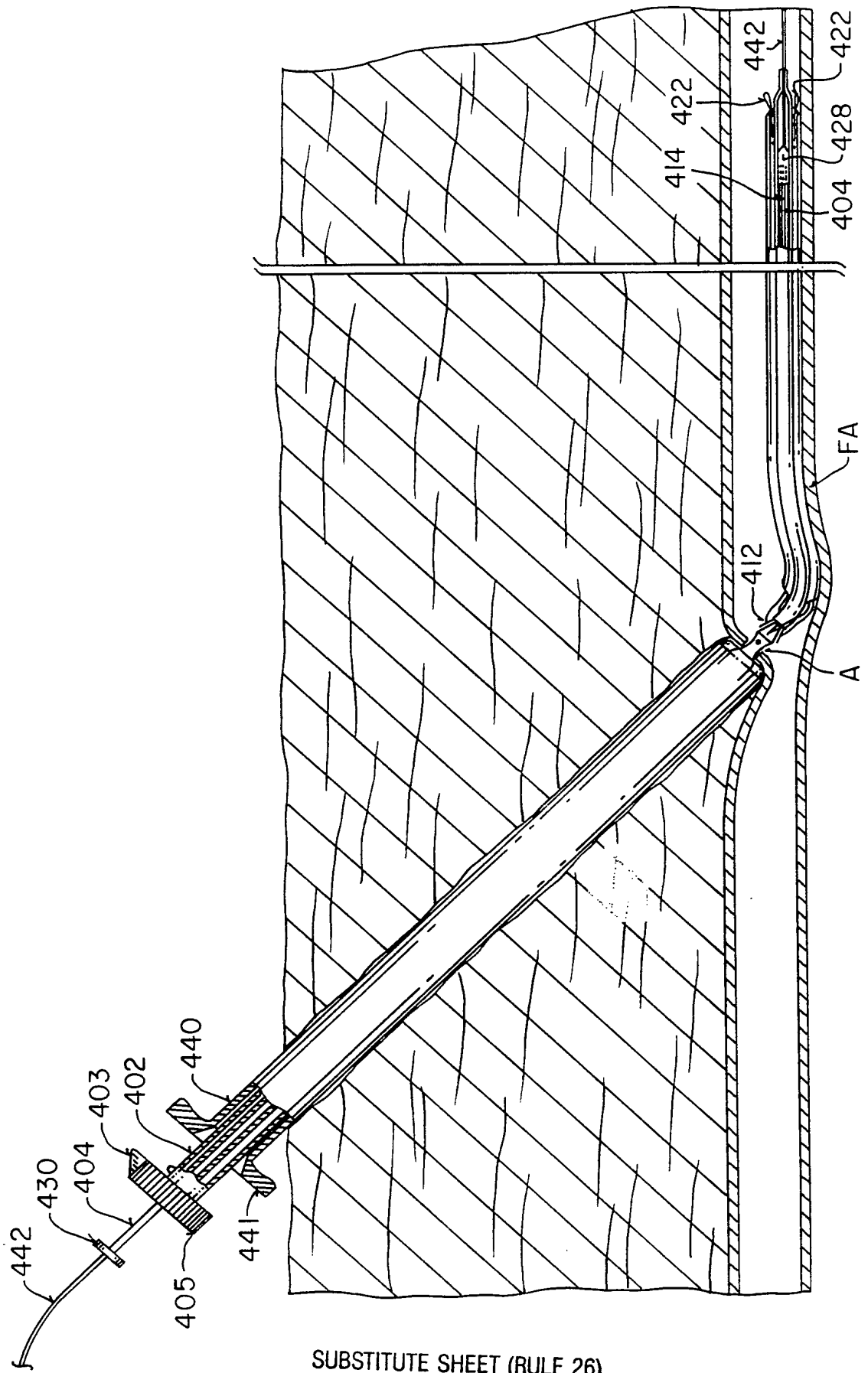
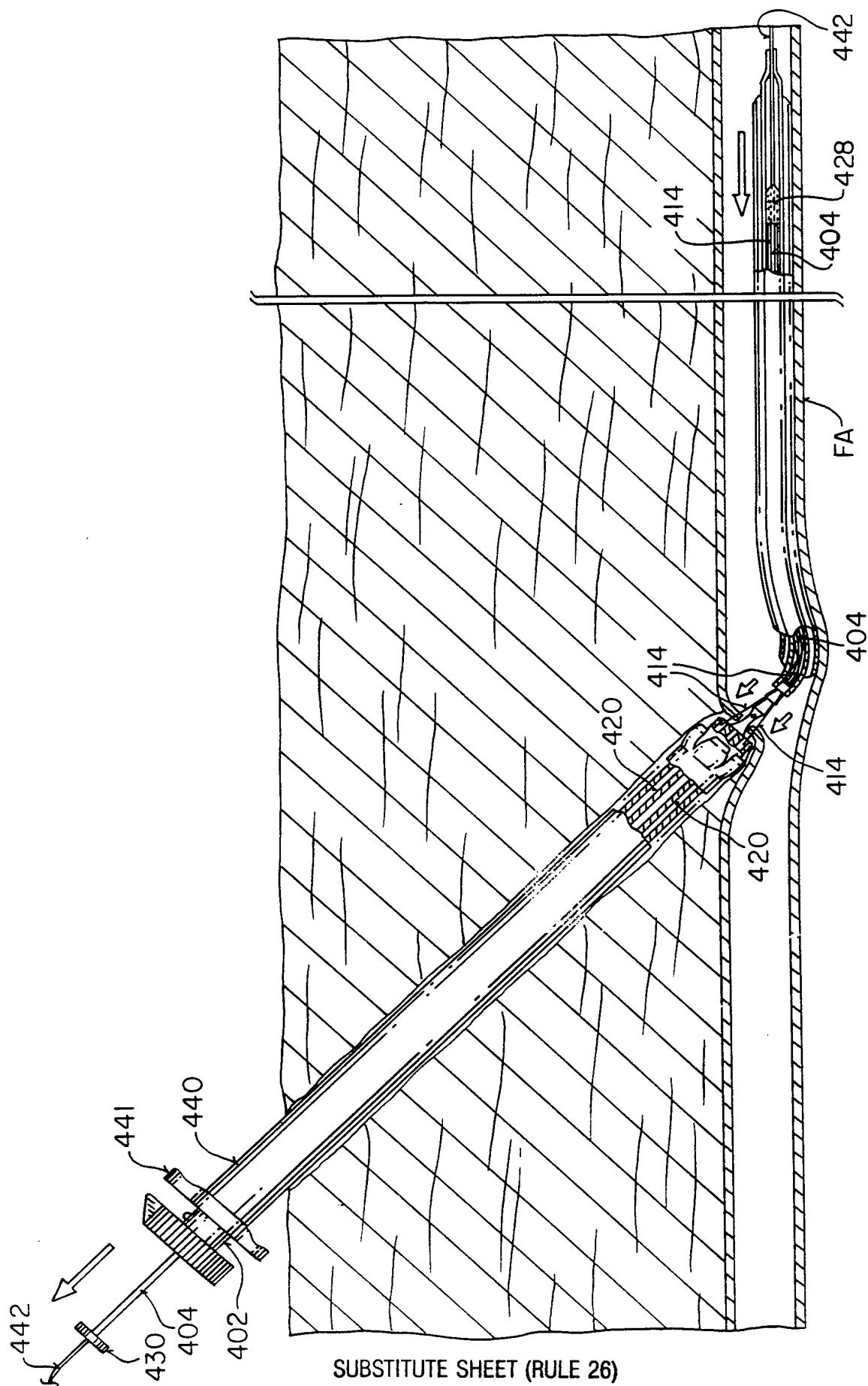


FIG. 38



SUBSTITUTE SHEET (RULE 26)

FIG. 40

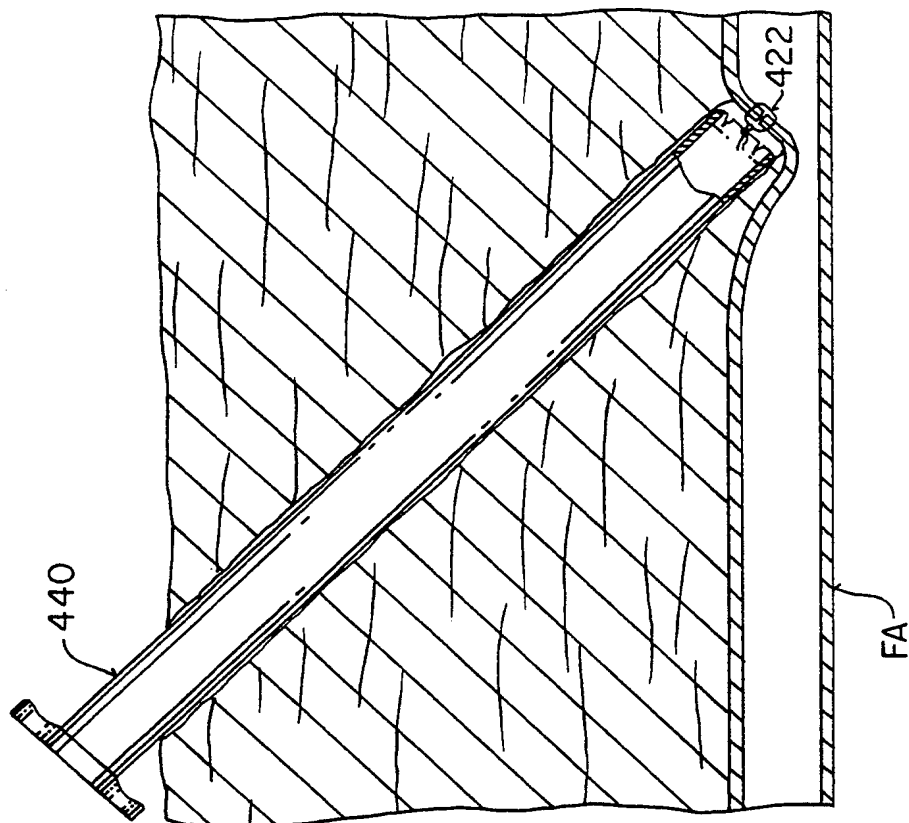
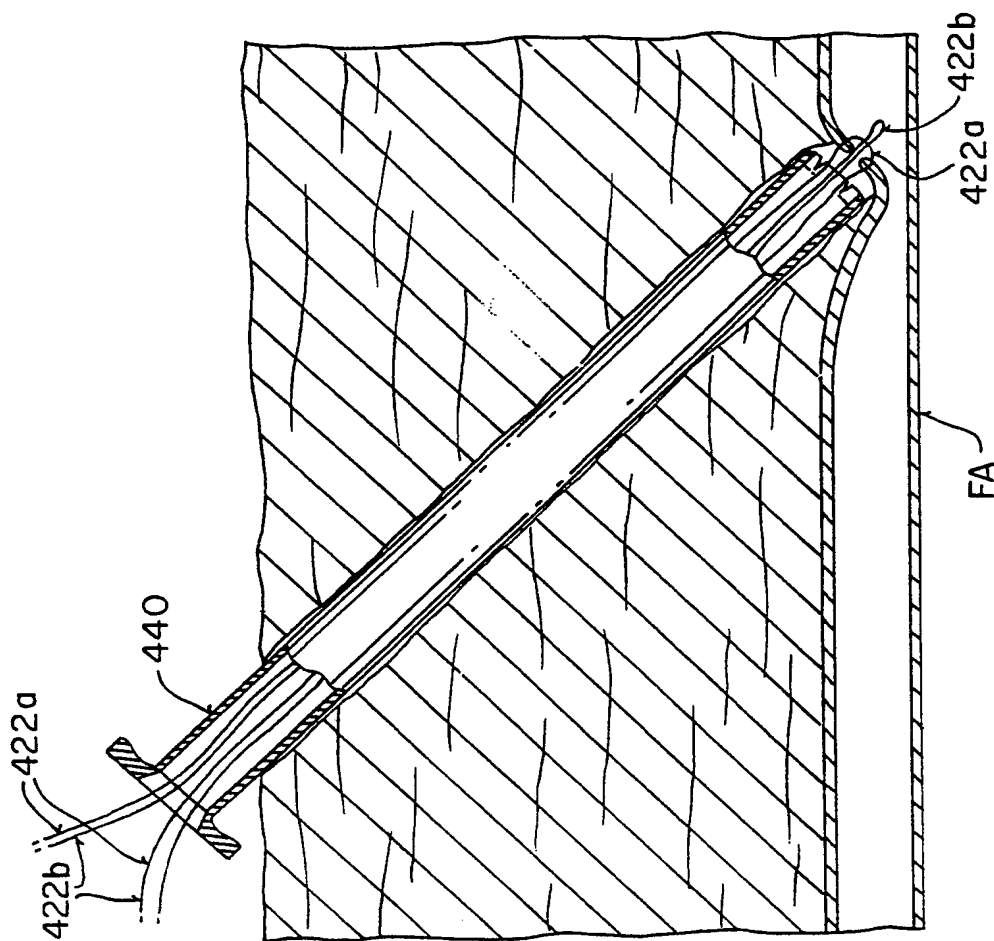


FIG. 39



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/11864

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 17/00

US CL : 606/144

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 144, 145, 147-148, 157-158, 184, 187, 222, 223; 112/169, 80.03; 604/168, 900

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,160,339, (CHEN et al.), 03 November 1992. See Figs. 2-3; and column 2 line 52 - column 3 line 47.	42
Y	US, A, 312,408, (G. WACKERHAGEN), 17 February 1885. See entire document.	7, 13, 34
X --- Y	"Innovation through progress", (REMA), 01 January 1992. See pages 1-4, REMA DEEP SUTURE I, and REMA DEEP SUTURE II.	1-3, 5-6, 8, 12, 16-18, 22-28, 30, 31, 33, 38, 41 ----- 7, 13, 34, 42

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be part of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* & * document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

25 JANUARY 1994

Date of mailing of the international search report

MAY 04 1994

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